SOMANETICS®

OPERATIONS MANUAL

INVOS® CEREBRAL OXIMETER
MODEL 5100B

Cerebral Oximeter Serial Number: 05-71322 .

Preamp Serial Number: 05-81322 .

WHENEVER THIS SYMBOL ⚠ *IS SEEN ON THE DEVICE, THIS MANUAL SHOULD BE CONSULTED FOR A COMPLETE EXPLANATION. PLEASE READ THIS MANUAL COMPLETELY BEFORE ATTEMPTING TO OPERATE THE DEVICE.*

THE INVOS® CEREBRAL OXIMETER IS EASY TO USE, HOWEVER, IT IS NECESSARY TO ADHERE TO THE WARNINGS AND SAFETY PRECAUTIONS IN CHAPTER 1 OF THIS MANUAL.

P/N 312971, Rev. A

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Description of Symbols


Attention; consult this manual for a complete explanation


Potential Equalization


Printer


Fuse


Recording on an information carrier (Disk Drive)


Alternating Current


Pause; Interruption


Dangerous Voltage


Stand-by


Type BF Equipment


Alarm


Do Not Reuse


Silence Alarm


Preamp

1010 Digital Output


Backup Battery


Sensor Light Source

Table of Contents

Chapter 1

Warnings/Cautions

NOTE: FEDERAL REGULATIONS IN THE UNITED STATES RESTRICT THE SALE OF THIS DEVICE TO OR ON THE ORDER OF LICENSED MEDICAL PRACTITIONERS.

Key Terms

rSO_2: Regional Saturation of Oxygen

INVOS®: Used in reference to the INVOS Cerebral Oximeter System

SomaSensor®: Used in reference to the patient applied component.

Pediatric (application for INVOS): Pediatric SomaSensor has been designed for use with pediatric patients weighing 4 – 40 kilograms.

Warnings

- Shock hazard: Do not attempt to perform any service or tamper with the warranty seal unless you have been authorized in writing by Somanetics. Repairs made by anyone not authorized by Somanetics during the warranty period will void the product warranty.
- Explosion hazard: Do not use the INVOS System in the presence of flammable anesthetics or in other flammable environments.
- Cross-contamination hazard: The SomaSensor is designed for single use only and may not be reused. Reuse may cause inaccurate readings, erratic readings, or no readings at all. Also reuse may cause an increased risk of cross-contamination among patients. Do not autoclave or gas sterilize the INVOS System or SomaSensor.
- Patient hazard: The SomaSensor is designed for external use only as described in the instructions. Do not use the SomaSensor internally for any reason.
- Shock hazard: Do not immerse the INVOS System in any liquids as they may cause electric shock hazard or damage the device.
- If the integrity of the external protective earth ground is in doubt, the INVOS System should be operated from the internal backup battery power source.
- Only make external connections to the types of equipment specified in the interfacing chapter of this manual (See Chapter 5). Connecting any other types of equipment may result in damage to the INVOS System or compromise its safety.
- Fire hazard: Do not block airflow to the bottom of the unit.
- Patient hazard: Preamplifier is magnetized. Do not place near pacemaker or implantable cardioverter-defibrillator (ICD).
- Backup battery is not user replaceable.

Precautions

- INVOS System readings represent a small volume of brain tissue beneath the SomaSensor and may not reflect oxygenation disturbances that occur elsewhere.
- Make sure all connectors are fully engaged and free from moisture. Moisture intrusion may cause inaccurate readings, erratic readings or no readings at all.
- Do not place the SomaSensor over sinus cavities, the superior sagittal sinus, subdural or epidural hematomas or other anomalies such as arteriovenous malformations, as this may cause readings that are not reflective of brain tissue or no readings at all.
- Use only Somanetics Corporation recommended or provided accessories. Use of the INVOS System with any untested sensor may compromise accuracy.
- If present in the blood, the following may cause inaccurate readings:
    - Cardiogreen or other intravascular dyes
    - Carboxyhemoglobin and other dyshemoglobins
    - Hemoglobinopathies
    - Bilirubinemia and/or icterus (jaundice)
- Use of an electrosurgical/electrocautery instrument in the vicinity of the INVOS System may interfere with the signal and result in no readings.
- Environments with excessive ambient light such as bright sunlight or strong operating room lighting may require covering the area of the SomaSensor with an opaque drape.
- In order to maintain full backup battery charge, the INVOS System must be plugged into AC mains power with the back panel AC mains power switch turned on. The front panel blue light will be illuminated on in this condition. Disconnect the INVOS System and briefly operate the unit periodically, to check the charge condition of the backup battery.
- Adult and Pediatric SomaSensors cannot be used simultaneously on the same monitor or a **REPLACE SENSOR** status message will appear.

Indications For Use

The noninvasive INVOS Cerebral Oximeter System is designed to noninvasively, directly and continuously measure and monitor changes in the approximate regional hemoglobin oxygen saturation in the microvasculature of the adult and pediatric brain. Since the hemoglobin in the sensor's field is made up of approximately 75% venous blood, 20% arterial blood and 5% capillary blood, the clinical interpretation of the readings is consistent with that of a venous measurement. The device is intended for use on any and all patients for whom there is concern regarding the potential for cerebral oxygen imbalances. It is intended for use by trained medical personnel only.

Contraindications

None.

Chapter 2

Specifications

Chapter Overview

This chapter provides product specifications for the INVOS System.

Specifications

Physical

		Oximeter	Preamp
Dimensions	Height	8.38 in (21.29 cm)	1.4 in. (3.56 cm)
	Width	9.63 in (24.46 cm)	3.75 in (9.53 cm)
	Depth	8.5 in (21.59 cm)	7.65 in (19.43 cm)
Weight		14 lbs (6.5 kg)	1.5 lbs (.75 kg)
Preamp Cable Length		15 ft (5 m)	
SomaSensor Cable Length		5 ft (1.52 m)	

Operational

Range	15 – 95 (updated every 5 – 6 seconds)
Repeatability	Hardware repeatability is within 1 rSO_2 index point from unit to unit including SomaSensor (measured in vitro).
Alarm Limit Range	High: 20 – 95; Low: 15 – 90 High and low limits cannot cross
Trend Memory	24 hours at 1 sample per minute 12 hours at 2 samples per minute
Diagnostics	Automatic self-test
Safety Class	Continuous Operation Type BF  Class I
Power	External AC mains or backup battery

Electrical

Input Voltage	100 – 240 V ~
Frequency	50/60 Hz
Current	1.0A – 0.5A (maximum at 100 and 240 volts respectively)
Fuse	F2.5A 250V
Backup Battery	Approximately 2 hours
Digital Output	RS-232 communications

Environmental Requirements

Operating Temperature	+60F to +90F (+16C to +32C)
Storage Temperature	-40F to 100F (-40C to +43C)
Humidity	20% - 80%, non-condensing
Altitude	To 10,000 feet (3,048 m)

Default Settings

	Default	Range
High rSO_2 Scale Limit	100	60-100 in increments of 10; 5 above High Alarm Limit
Low rSO_2 Scale Limit	30	0-60 in increments of 10; 5 below Low Alarm Limit
High Alarm Limit	90	20-95
Low Alarm Limit	40	15-90
Trend Scale	1 hour	1, 2, 4, 8, 12, 24 hours
Trending Rate	2 per minute	1 or 2 per minute
Alarm Volume	Medium	Low, Medium, High
Disk Storage:	(No Default)	10, 20, 30 or 60 seconds

NOTE: SPECIFICATIONS SUBJECT TO CHANGE WITHOUT NOTICE TO USER.

Compliance With Standards

The INVOS System complies with the following U.S. and international regulatory standards for medical equipment:

CE 0197
EN60601-1-2 (IEC 601-1-2)
UL2601.1
CSA 22.2 No. 601.1

Somanetics Corporation's quality system is registered to the ISO 9001 standard.

Chapter 3

Before You Begin

Chapter Overview

This chapter provides information that the user should know before attempting to operate the INVOS System.

How to Use this Manual

As well as complying with the warnings previously listed in Chapter 1, please consult this manual for operation and maintenance instructions. Read the manual completely before using the INVOS System to ensure proper, safe operation. Do not attempt to repair the INVOS System during the warranty period. Somanetics should make repairs during the warranty period.

Background

The INVOS Cerebral Oximeter is designed to noninvasively, directly and continuously measure and monitor changes in the approximate regional hemoglobin oxygen saturation in the microvasculature of the brain. The device is intended for use on any and all patients for whom there is concern regarding the potential for cerebral oxygen imbalances. It is intended for use by trained medical personnel. It uses the principle of near-infrared spectroscopy, similar to pulse oximetry, but does not depend on a pulsatile signal to provide approximate measurement and trending of changes over time of regional oxygen saturation in the brain. Therefore, the device could be expected to operate effectively during periods of peripheral shutdown, low blood pressure, hypothermia, cardiopulmonary bypass and circulatory arrest (i.e. periods when pulse oximeters may fail).

No effort is made to separate pulse-gated changes in optical absorption caused by arterial blood from the background absorption, making the measurement an aggregate of the arterial, venous and capillary oxygen saturation. However, since 75% of the blood in the field of measurement is venous,[1,2,3] the measurement provides a predominantly venous saturation, reflecting the balance between cerebral oxygen delivery and oxygen consumption.

A small, medical-grade adhesive, single-patient use sensor is attached to the forehead and serves as the emitter and detector of the light. At the wavelengths of interest, the light penetrates skin, bone and tissue relatively easily.[4] The predominant chromophore, hemoglobin, absorbs specific wavelengths of light in a manner which enables the measurement of oxygen-bound hemoglobin and reduced hemoglobin in the field, generating a number intended to represent the approximate oxygen saturation of the predominantly venous microvasculature.

Near-infrared light of suitable wavelengths is produced by miniature light-emitting diodes in the sensor. The scattering nature of the sampled tissues causes the photons to travel random paths through the brain; however, computerized simulations reveal an average path consisting of an ellipse between emitter and detector.[5] Two photodiodes serve as the detectors and are arranged on the sensor at different distances from the light source. Since the depth of penetration of the average light beam is proportional to the distance from the light source,[6] the

measurement can be depth resolved, allowing simultaneous monitoring of differing tissue strata. The farther detector measures the saturation in all of the tissue penetrated by the light beam, including skin, skull and muscle tissue as well as brain. The closer detector makes much the same measurement except it receives light which has not penetrated as deeply. The two photon paths are most alike for small tissue depths but are quite different at the maximum depth of penetration as related to the farther spacing. The common path can be used to suppress signals not representative of brain tissue to produce rSO_2.

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1 Moskalenko YE, Weinstein GB, Demchenko IT, et al: Biophysical aspects of the cerebral circulation. In: Cooper R, ed. The biophysical organization of the system of the cerebral circulation. Oxford: Pergamon, 1980:41-57.

2 Mchedlishvili G: Arterial behavior and blood circulation in the brain. New York: Plenum Press, 1986:55-60.

3 Wiederhold KH, Bielser W, Schultz U, Veteau MJ, Hunziker O: Three dimensional reconstruction of brain capillaries from frozen serial sections. Microvasc Res 1976; 11:175-180.

4 Eggert HR, Blazek V: Optical properties of human brain tissue, meninges, and brain tumors in the spectral range of 200 to 900 nm. *Neurosurgery* 1987;21:459-464.

5 Van der Zee P, Delpy T. Simulation of the point spread function for light in tissue by a Monte Carlo Model. Adv Exp Med Biol 1987;215:191-198.

6 Bonner RF, Nossal R, Weiss GH: The influence of path length on remote optical sensing of properties of biological tissue. *Appl Optics* 1989;28:2238-2244.

Application to the INVOS

The INVOS Cerebral Oximeter provides noninvasive, continuous and direct information on regional cerebral oxygen saturation. The measurement takes place in real time, providing an immediate indication of a change in the critical balance of oxygen delivery and oxygen consumption.

Spectroscopic measurements are collected continuously, averaged numerically and used to calculate data points. After approximately 5 seconds, the screen is updated to display a new rSO_2 saturation value. Alarm notification, consisting of visual and audible indicators, appears immediately following display of a saturation value outside the user-adjusted high or low limits. An on-screen trend display is updated every 30 or 60 seconds (user selectable) and each point represents the most recent displayed saturation value at the time it is added. This trend can be adjusted to display variable lengths of stored data from one hour to 24 hours.

A real-time and stored data RS-232 output is available for communication with other devices. In real time, RS-232 sends a new saturation value approximately every 5 seconds, which also represents the most recent displayed value. It will download a full memory in about 1.5 minutes.

A printer and disk drive output is included which allows connection of a compatible printer or disk drive for documentation purposes. The printer and disk drive outputs are designed to download all of the stored data on command, producing a record of up to 24 hours of cerebral saturation monitoring on paper or 3.5" floppy disk in ASCII text file data format. The printer will download in real-time approximately every 5 seconds or a full memory in approximately 45 minutes. In real-time, the disk drive will store data at a storage rate of every 10, 20, 30 or 60 seconds. The disk drive will download full memory, up to 24 hours, of stored data in approximately 1 minute.

SomaSensor

The SomaSensor is a disposable, non-sterile transducer capable of producing and detecting optical data from the patient, converting that data to electrical signals and sending them to the

INVOS System. It is applied to the forehead via self-contained, medical-grade adhesive. Electrical signals from the photodiodes are sent through the shielded cable to the INVOS System for processing.

The SomaSensor is designed for single use only and may not be reused. Reuse of the SomaSensor may cause inaccurate readings, erratic readings, or no readings at all. Also, reuse may cause an increased risk of cross-contamination.

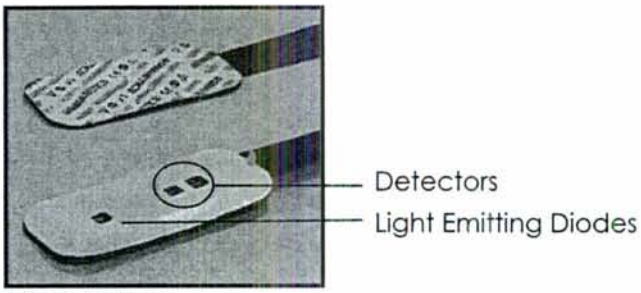


Figure 3.1 SomaSensor

CAUTION: MAKE SURE ALL CONNECTORS ARE FULLY ENGAGED AND FREE FROM MOISTURE. MOISTURE INTRUSION MAY CAUSE INACCURATE READINGS OR NO READINGS AT ALL.

Use of Product

Do not use this product if it is found defective in any way; contact a Somanetics Customer Service Representative for repair or replacement. If the INVOS System is not operated, maintained and repaired in compliance with this manual (including product inserts and warnings), it will not function as described. The user is responsible for operating and maintaining the INVOS System according to instructions outlined in this manual. The manufacturer (Somanetics) is not responsible for injury or losses if the INVOS System is not used in compliance with instructions.

Customer Inquiries

For any questions regarding the INVOS System safety and effectiveness or any other information, please contact the Somanetics Customer Service Department at (248) 689-3050, ext. 255 or (800) 359-7662 or customerservice@somanetics.com.

Service and Repair

If the INVOS System fails to operate as stated, it should be taken out of service immediately. See Chapter 10 for troubleshooting techniques.

WARNING: DO NOT ATTEMPT TO PERFORM ANY SERVICE OR TAMPER WITH THE WARRANTY SEAL UNLESS YOU HAVE BEEN AUTHORIZED IN WRITING BY SOMANETICS. REPAIRS MADE BY ANYONE NOT AUTHORIZED BY SOMANETICS DURING THE WARRANTY PERIOD WILL VOID THE PRODUCT WARRANTY.

If the problem cannot be solved, follow the steps below to obtain service:

1. Contact a Somanetics Customer Service Representative at:

   Customer Service Department
   Somanetics Corporation
   1653 East Maple Road
   Troy, MI 48083-4208
   Phone: (248) 689-3050, ext. 255
   Fax: (248) 689-4272
   Email: customerservice@somanetics.com
   Website: http://www.somanetics.com

2. Obtain a Return Material Authorization (RMA) number from the Somanetics Customer Service Representative.

When returning an INVOS System, ship it prepaid, in the original container as received, if possible. **It is important to use the original container and packing material to prevent damage to the unit in shipping.** Somanetics will not assume responsibility for damage caused in shipment if the customer does not use original shipping materials. Shipping materials can be obtained by contacting Somanetics' Customer Service Department. Also include:

- Detailed description of the problem or need.
- RMA number and serial number of the unit.
- Name and phone number of the person to contact within your facility.
- Information regarding where and to whom to address the return of the INVOS System.
- All accessories that came with the product: Preamp, AC Line Cord, and any other optional attachments.

NOTE: FOR ADDITIONAL WARRANTY AND REPAIR INFORMATION SEE CHAPTER 9.

Chapter 4

Installation

Chapter Overview

This chapter provides information for unpacking and setting up the INVOS System.

Unpacking

NOTE: BE SURE YOU MEET ALL ENVIRONMENTAL REQUIREMENTS BEFORE UNPACKING THE UNIT. SEE THE SPECIFICATIONS IN CHAPTER 2 FOR MORE DETAILS.

1. Inspect the shipping container visually for signs of damage or abuse during transit.
2. Carefully unpack the unit and all accessories. Be sure you have the following pieces:
   - Cerebral Oximeter
   - Preamp
   - Bilateral Reusable Sensor Cable
   - Power Cord
   - Operations Manual
   - Any other accessories you may have ordered

NOTE: SAVE THE BOX AND PACKING MATERIAL FOR ANY FUTURE TRANSPORT.

3. Remove all tape and packing materials from the unit and accessories.
4. Visually inspect the unit and accessories for signs of shipping damage. If there is damage, report it to the shipping carrier (UPS, FedEx, or other) immediately.
5. Record the Cerebral Oximeter and Preamp serial numbers on the inside cover page of this manual. The INVOS System serial number appears on the Cerebral Oximeter back panel. The Preamp serial number appears on the back of the Preamp.

NOTE: UPON INITIAL UNPACKING, THE BATTERY MAY BE PARTIALLY DISCHARGED. BEFORE ATTEMPTING BATTERY OPERATION, THE BATTERY MUST BE CHARGED BY CONNECTING THE UNIT TO AC POWER IN EITHER OPERATIONAL OR NON-OPERATIONAL MODES. A CHARGE TIME OF 15 HOURS IS REQUIRED TO RECHARGE A DISCHARGED BATTERY. THE BLUE ∿ INDICATOR ON THE KEY PANEL INDICATES WHEN THE BATTERY IS RECEIVING VOLTAGE TO CHARGE.

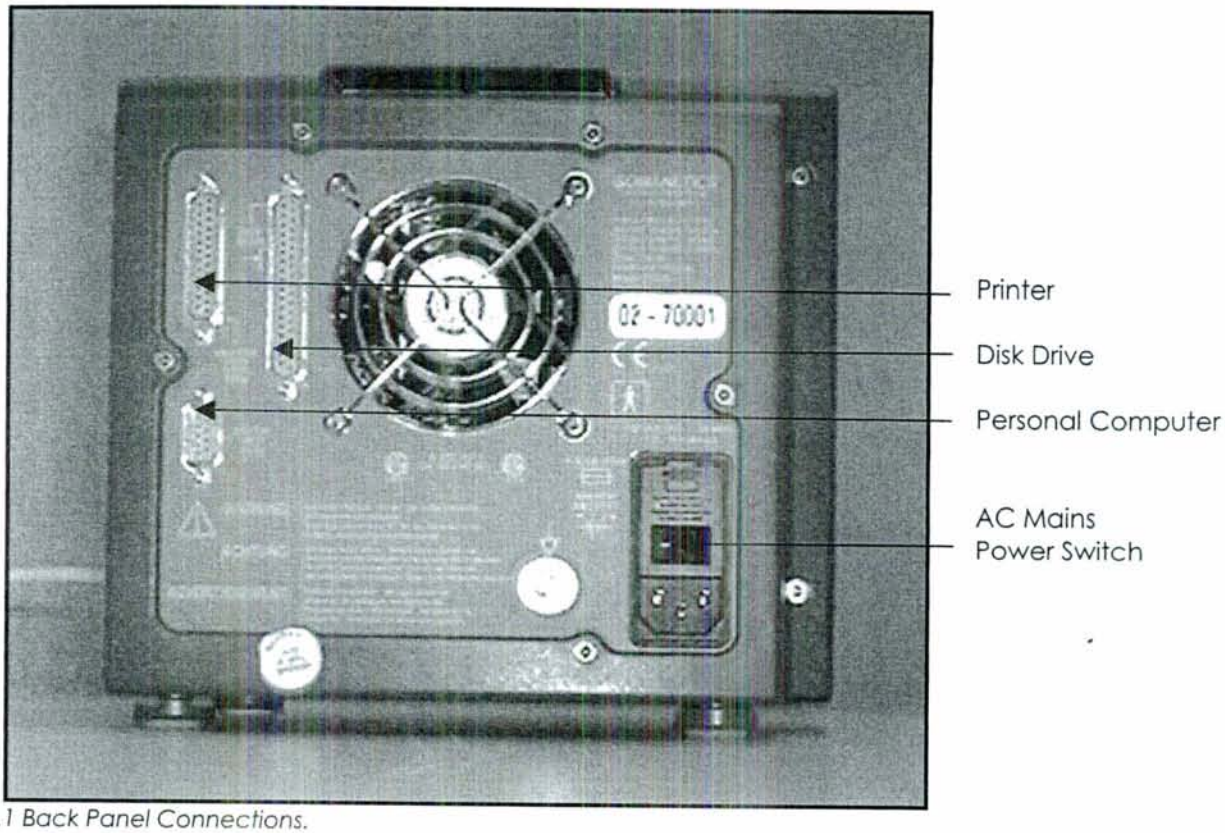


Figure 4.1 Back Panel Connections.

NOTE: USE ONLY HOSPITAL GRADE AC MAINS OUTLETS.

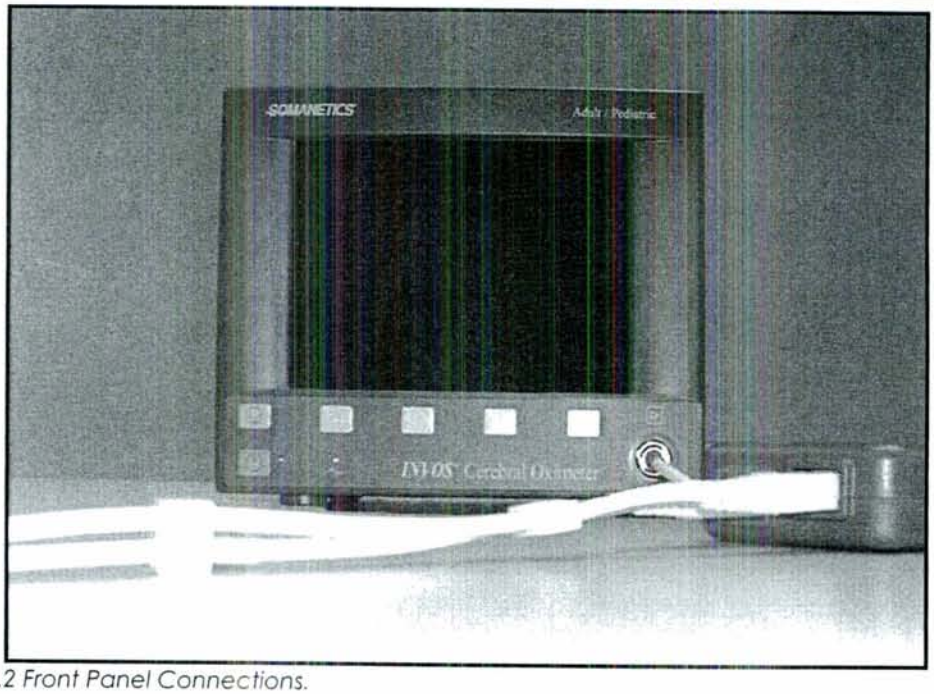


Figure 4.2 Front Panel Connections.

Installation - Basics

1. Place the INVOS System on a sturdy flat surface or attached to optional stand.

WARNING: IF THERE IS A CHANCE OF THE UNIT FALLING, IT MUST BE PERMANENTLY SECURED.

2. Attach appropriate cables to connections shown in Figures 4.1 and 4.2.
3. Power up the unit by turning on the line power switch on the rear panel (indicated by the blue light on front panel) and pressing the power button on the front panel.

NOTE: THE LINE POWER SWITCH (ON THE BACK PANEL OF THE UNIT) MUST BE LEFT ON AND AC POWER MUST BE CONNECTED AT ALL TIMES TO MAINTAIN THE BATTERY AT FULL CHARGE. THE ∿ BLUE AC POWER INDICATOR SHOWS POWER SWITCH IS ON.

4. Verify that the screen displays system messages.
5. Connect two SomaSensors to the Preamp. Refer to Chapter 6 for complete information.
6. Check for light in the sensor LED compartment (the opening farthest from the cable).
7. Complete the Pre-use Checklist in Chapter 6.

NOTE: FOR COMPLETE SETUP AND OPERATING INSTRUCTIONS SEE CHAPTERS 5, 6, 7 AND 8.

Accessories

Order Number	Description
BRCB	Bilateral Reusable Sensor Cable for use with SomaSensor Models SAFB and SPFB only
SAFB	SomaSensor for Adults (>40 kg)
SPFB	SomaSensor for Pediatrics (4 – 40 kg)
312970	Additional Operations Manual, INVOS Cerebral Oximeter, Model 5100B
312988	Service Manual, INVOS Cerebral Oximeter, Model 5100B
4100-FTD	Field Test Device, INVOS Model 4100, 5100 and 5100B
5100B-W	One Year Warranty Extension, INVOS Model 5100B
4100-STD	Portable Stand, INVOS Models 4100, 5100 and 5100B
4100-TC	Travel Case, INVOS Models 4100, 5100 and 5100B
4100-DPU-414	Thermal Printer, INVOS Models 4100, 5100 and 5100B
312109	Thermal Paper, Case of 5 rolls
4100-DD	Disk Drive, INVOS Models 4100, 5100 and 5100B
DB9DB9	Null Modem Cable (for Digital Output), INVOS Models 4100, 5100 and 5100B

Accessories can be ordered by contacting Somanetics Customer Service at (800) 359-7662 in the United States or (248) 689-3050, ext. 255 or via the Internet at http://www.somanetics.com.

WARNING: ACCESSORIES NOT SUPPLIED BY SOMANETICS MAY NOT MEET EN60601-1-2 (IEC 601-1-2) STANDARDS. CONTACT SOMANETICS' CUSTOMER SERVICE DEPARTMENT AT (248) 689-3050, EXT. 255 OR customerservice@somanetics.com FOR COMPATIBLE PRODUCTS THAT MAY MEET THESE REQUIREMENTS.

Chapter 5

Interfacing with the INVOS System

Chapter Overview

This chapter provides information on the features and specifications of the front and back panel buttons and connections of the INVOS System.

WARNING: ALL EQUIPMENT USED WITHIN TWO (2) METERS OF THE PATIENT (PATIENT ENVIRONMENT) MUST BE IEC-601 APPROVED. ALL EQUIPMENT USED OUTSIDE THE PATIENT ENVIRONMENT MUST BE APPROVED TO THE APPROPRIATE IEC OR ISO STANDARDS (E.G.: IEC 950 FOR OFFICE EQUIPMENT).

Front Panel

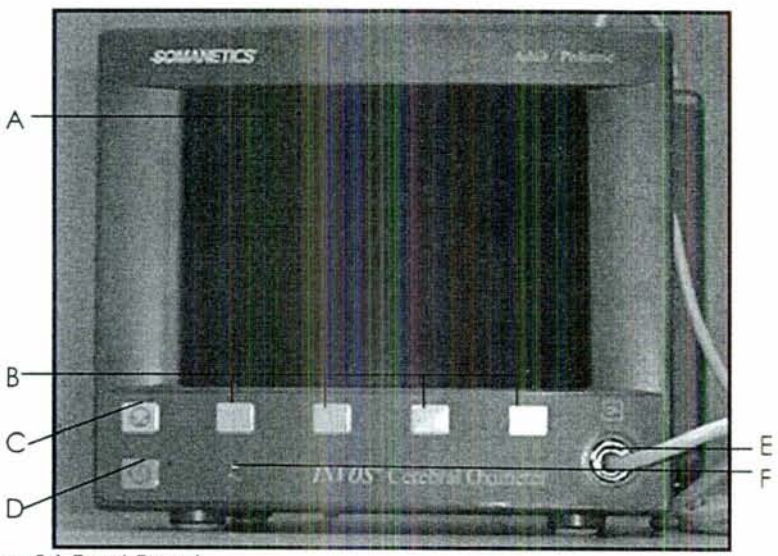


Figure 5.1 Front Panel.

A. **Display Screen** - Displays the rSO_2 %, trend data, system status, alarm limits, rSO_2 limits, date and time. Also displays menus for default parameter changes, alarm messages and data trending rate.

B. **Menu Keys** - Allows the operator to change available options as needed.

C. **RUN/PAUSE** - The INVOS System will not display rSO_2, alarm or store data in the Pause mode. Pause mode will read **"PAUSED"** on the display. The RUN/PAUSE key must be pressed again to resume monitoring and information storage.

D. **ON/OFF** - Lower left key turns power to the INVOS System on and off.

E. **PREAMP** - This is the input for the Preamp (See Chapter 5).

F. **CHARGE** - A blue LED indicates when the unit is receiving sufficient voltage to charge the battery. When this light is ON, the unit is operating from AC power. When this light is OFF, the unit is operating from battery power.

NOTE: CHECK THE REAR PANEL POWER SWITCH AND POWER CORD IF THE CHARGE LIGHT IS NOT ON.

Preamp

The Preamp provides an electrically isolated connection for the SomaSensor. The 15-foot long Preamp cable attaches to the **PREAMP** connection on the front panel of the INVOS Oximeter. At the other end of the Preamp is the patient connection to attach the bilateral reusable cable and SomaSensors. A diagram of the Preamp is shown in Figure 5.2. For complete setup information see Chapter 5.

WARNING: PREAMPLIFIER IS MAGNETIZED. DO NOT PLACE NEAR PACEMAKER OR ICD.

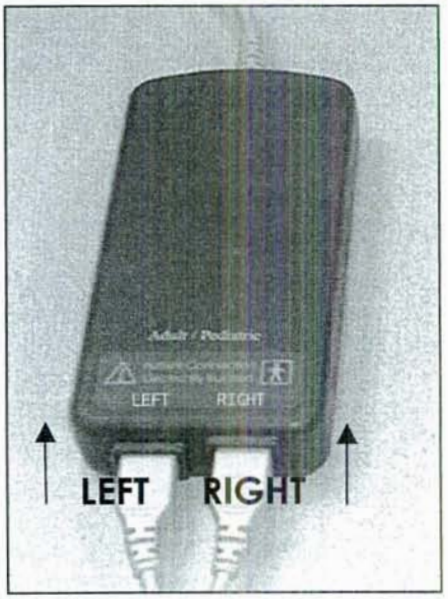


Figure 5.2 Preamp

Bilateral Reusable Sensor Cable

The Bilateral Reusable Sensor Cable connects the SomaSensors to the Preamp. The Sensor Cable is intended for multiple use and should not be discarded. However, the SomaSensor is single-patient use only.

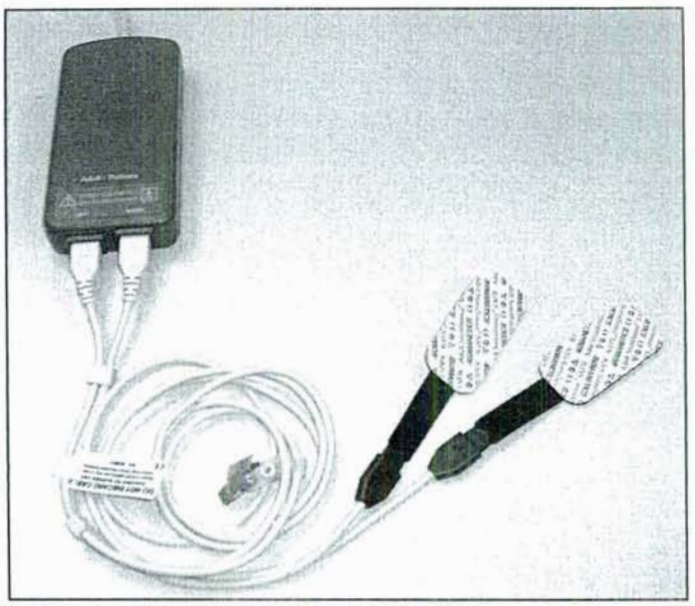


Figure 5.3 Bilateral Reusable Sensor Cable

Back Panel

The INVOS System back panel (Figure 5.4) contains the following elements:

A. Printer Output Port (Parallel)

B. Digital Output Port (RS-232) **1010**

C. Cooling Fan

D. Disk Drive Port

E. AC Input, Fuse and Power Switch (must be turned on to keep battery charged.)

F. Potential Equalization Connector

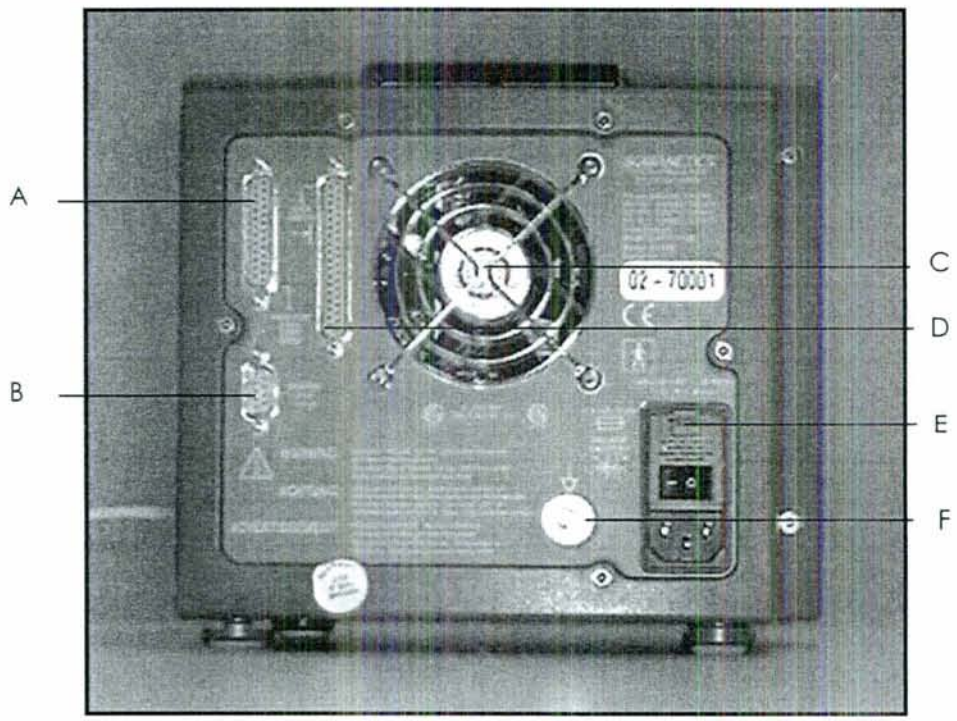


Figure 5.4 Oximeter Back Panel

WARNING: ACCESSORIES NOT SUPPLIED BY SOMANETICS MAY NOT MEET EN60601-1-2 (IEC 601-1-2) STANDARDS. CONTACT SOMANETICS' CUSTOMER SERVICE DEPARTMENT AT (248) 689-3050, EXT. 255 OR customerservice@somanetics.com FOR COMPATIBLE PRODUCTS THAT MAY MEET THESE REQUIREMENTS.

Printer Output Port

The printer output allows data from the INVOS System to be transferred to paper. This port is a standard centronics parallel output. The printer communication protocol is designed to support the INVOS Thermal Printer available from Somanetics. Other printers that meet the appropriate IEC or ISO standards and emulate the Seiko graphics character set also may be suitable. The maximum time required to print a 24-hour record for the INVOS Thermal Paper Printer is approximately 60 minutes. See Chapter 8 for instructions.

Disk Drive Port

The disk drive port allows data from the INVOS System to be transferred to an IBM formatted

DS/HD 3.5" floppy disk. The communication protocol is designed to support the INVOS Disk Drive available from Somanetics. See Chapter 8 for instructions.

NOTE: USE ONLY A SOMANETICS SUPPLIED DISK DRIVE WITH THE INVOS SYSTEM. NO OTHER DISK DRIVE DEVICES SHOULD BE CONNECTED TO THE INVOS SYSTEM. FOR ADDITIONAL INFORMATION ON ACQUIRING AND USING THE DISK DRIVE UNIT, CONTACT SOMANETICS' CUSTOMER SERVICE DEPARTMENT AT (248) 689-3050, EXT. 255 OR customerservice@somanetics.com FOR COMPATIBLE PRODUCTS THAT MAY MEET THESE REQUIREMENTS.

Digital Output Port - 1010

This port provides real time and stored digital data communications with other devices such as a PC. Consult Somanetics for compatibility with other commercial devices. See Chapter 8 for instructions.

AC Input and Fuse ∿ ⊟

The AC Input provides a connection for AC power. The INVOS System will operate on 100-240 V ∿ with a frequency of 50/60 Hz.

The AC Input also has an ON/OFF switch which turns AC power to the unit on and off. When AC power is connected, this switch must be in the 'ON' position to run the unit from AC power. When the switch is in the 'ON' position, the blue 'CHARGE' light will be illuminated on the front panel. If this switch is in the 'OFF' position, the unit can only be operated from battery power.

CAUTION: WHEN THE INVOS SYSTEM IS NOT IN USE, THE AC POWER SWITCH MUST BE TURNED ON WITH AC POWER CONNECTED IN ORDER TO KEEP THE BATTERY CHARGED.

Above the ON/OFF switch is the external access fuse compartment. The AC input line is fused with 2.5A, 250V fuses.

WARNING: DISCONNECT AC POWER CORD BEFORE OPENING FUSE COMPARTMENT DOOR.

Remove the fuse holder by inserting a jeweler's size flat-blade screwdriver into the slot at the top of the holder and pry out. Remove the fuse holder from the line filter. To replace the fuses, place the new fuse in the side of the holder with one end closest to the four posts at the back of the holder. The other end of the fuse should go to the middle of the fuse holder and latch into the middle fuse holder spot. When both fuses are installed, place the fuse holder back in the line filter and push it in completely. Close the fuse compartment door. (See Figure 5.5)

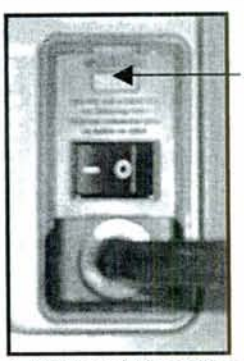


Figure 5.5 AC Input Line Filter Fuse.

Potential Equalization Connector ⏚

The Potential Equalization Connector (Grounding Post) provides a redundant external connection to earth ground if necessary.

Alarm Speaker Output

The Alarm Speaker Output provides an audio output signal to alert the operator to problems and alarms that may occur while monitoring (See Chapter 6).

Cooling Fan

The Cooling Fan provides air circulation through the INVOS Oximeter. Cooling air enters through the vents in the bottom of the monitor and exhausts through the fan. Do not block the cooling air intake vents or fan exhaust. The no maintenance, ball bearing fan rotates at 1500 rpm.

Chapter 6

Operating the Unit

Chapter Overview

This chapter provides instructions on how to operate the INVOS System. Read this chapter completely before attempting to operate the unit.

Getting Started

WARNING: THE SOMASENSOR® IS DESIGNED FOR USE WITH THE INVOS CEREBRAL OXIMETER MODEL 4100 AND 5100 SERIES. USE OF THE SOMASENSOR WITH ANY OTHER DEVICE MAY COMPROMISE PATIENT SAFETY.

A visual inspection of the INVOS System and SomaSensor must be performed prior to use. Visually inspect the following:

- The INVOS System case and screen should be clean and show no signs of damage.
- The Power Cord and Preamp cable should show no signs of damage.
- The Sensor Connector and Preamp receptacle should be clean and show no signs of damage.
- Check the Bilateral Reusable Sensor Cable connector (pins should not be bent.)

INVOS System Setup

Figure 6.1 Oximeter Preamp Connection.

Connect the Preamp to the front panel connection on the INVOS Oximeter. To do this, hold the connector at the end of the Preamp cable with the red dot facing up. Align the red dot on the connector with the red dot on the front panel connection. Insert the cable connector into the front panel connection while keeping the red dots aligned. Be sure to fully insert the connector until it locks.

CAUTION: DO NOT TWIST OR BEND THE CONNECTOR WHILE INSERTING. THE CONNECTOR SHOULD BE PUSHED STRAIGHT IN WITHOUT NEED FOR EXCESSIVE FORCE.

If the connector will not fully enter the front panel connection, remove it and examine for any defects in both components. If both components show no signs of damage, realign the red dots and try again.

CAUTION: MAKE SURE ALL CONNECTORS ARE FULLY ENGAGED AND FREE FROM MOISTURE. MOISTURE INTRUSION MAY CAUSE INACCURATE READINGS OR NO READINGS AT ALL.

To disconnect the Preamp draw back on the locking sleeve and detach Preamp.

Connect the Bilateral Reusable SomaSensor Cable to the Preamp as shown in Figure 6.2.

CAUTION: MAKE CERTAIN TO CONNECT THE SENSOR CABLE CONNECTOR MARKED "LEFT" TO THE PREAMP CONNECTOR MARKED "LEFT" AND THE SENSOR CABLE CONNECTOR MARKED "RIGHT" TO THE PREAMP CONNECTOR MARKED "RIGHT."

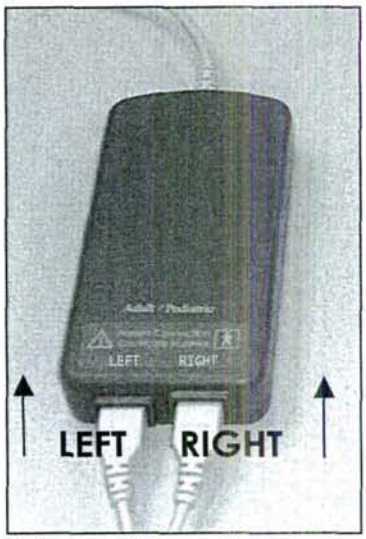


Figure 6.2 Preamp Connection.

Turn the INVOS System **ON**. The INVOS System will sequence through a series of start-up and self-test screens and will stop at the following screen:

Figure 6.3 NEW PATIENT/PREVIOUS PATIENT Screen.

Select **NEW PATIENT** or **PREVIOUS PATIENT** by pressing the button beneath the appropriate prompt. Monitoring will begin. Take care to place the sensor to be adhered to the right forehead in the Preamp connector labeled "RIGHT" and the sensor to be adhered to the left forehead in the Preamp connector labeled "LEFT."

Software Version

The INVOS Cerebral Oximeter application software version appears on the Start Screen, where **XX.XX.XX** is shown in Figure 6.3.

Serial Numbers

The INVOS System serial number appears on the Cerebral Oximeter back panel. The Preamp serial number appears on the back of the Preamp.

Sensor Lot Number

The sensor lot number appears on the individual sensor packaging.

Applying the Sensor

The sensor is supplied pre-calibrated and is easily and quickly applied to the patient's forehead with self-contained, medical-grade adhesive.

Remove two sensors from their packages and examine for visual signs of damage. If any signs of damage are observed, select another sensor.

Remove any moisture or perspiration from the patient's forehead with a dry gauze pad. **Then, degrease the skin using the enclosed skin prep pad. Discard skin prep pad after single use.** Ensure the patient's forehead is completely dry and remove any degreaser residue, if any, with a dry gauze pad.

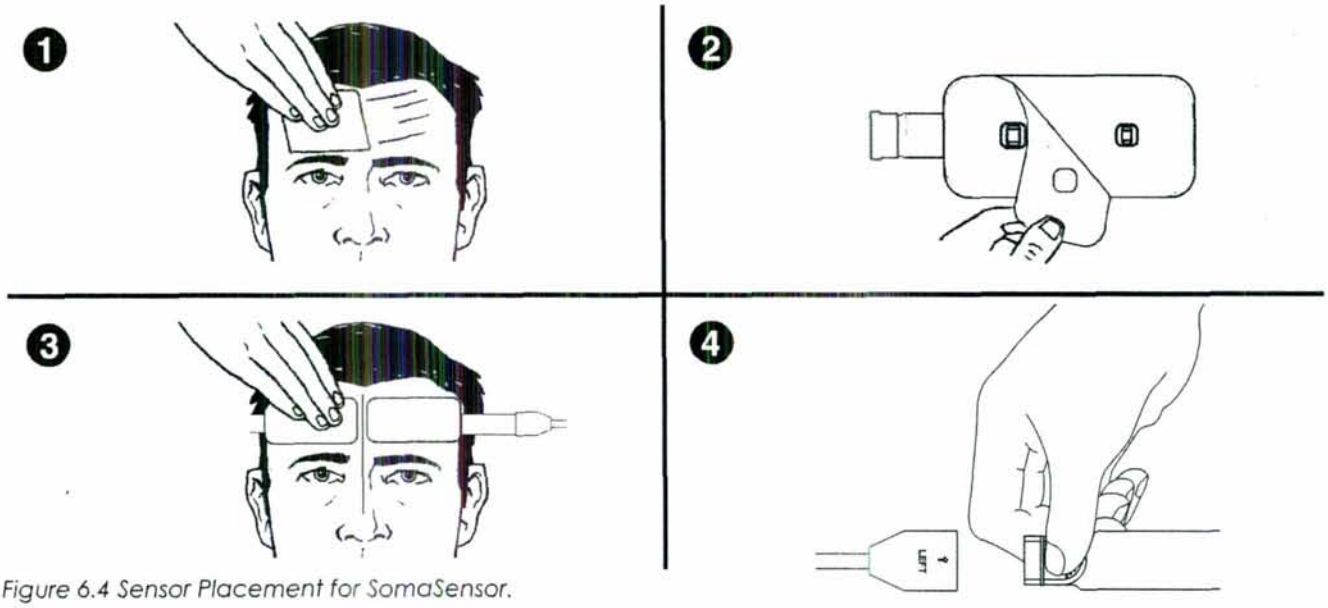


Figure 6.4 Sensor Placement for SomaSensor.

Select sensor site on right or left or both sides of forehead (site selection will determine which region of the brain is monitored). Placement of the sensor in other locations, or over hair, may cause inaccurate readings, erratic readings, or no readings at all. **Do not** place the SomaSensor over sinus cavities, the superior sagittal sinus, subdural or epidural hematomas or other anomalies such as arteriovenous malformations, as this may cause readings that are not reflective of brain tissue or no readings at all.

Remove the protective backing label from the adhesive side of the sensor and apply to the forehead as illustrated in Figure 6.4. The edge of the sensor opposite the cable exit must be positioned medially with the cable placed laterally. To avoid positioning over sinus cavities, keep the sensor high and lateral on the forehead above the eyebrow without positioning over hair.

Continue applying the sensor by smoothing it to the forehead from the center outward.

Make certain edges of the sensor are sealed to forehead to prevent light from entering.

Secure the cable to a fixed object to avoid strain on the sensor to skin interface using strain relief clips.

Figure 6.5 Strain Relief Clips

Connect SomaSensors to the Bilateral Reusable Sensor Cable as illustrated in Figure 6.4.

CAUTION: HOLD SENSOR CONNECTOR AND DO NOT BEND THE RIBBON CABLE WHILE INSERTING.

CAUTION: MAKE SURE ALL CONNECTORS ARE FULLY ENGAGED AND FREE FROM MOISTURE. MOISTURE INTRUSION MAY CAUSE INACCURATE READINGS OR NO READINGS AT ALL.

The INVOS System is now ready for use. When the SomaSensors are properly attached, the real time display of rSO_2 % can be viewed following a five (5) second delay which allows the INVOS System to read the sensor calibration data. The INVOS System will automatically re-read the sensor calibration data and continue running if communication with the Preamp is interrupted.

*NOTE: MAKE SURE **SYSTEM SIGNAL OK** APPEARS IN THE STATUS AREA ABOVE EACH rSO_2 % VALUE. WHEN THIS MESSAGE IS DISPLAYED, THE SYSTEM IS FUNCTIONING PROPERLY.*

WARNING: STRONG OUTSIDE LIGHT SOURCES MAY PREVENT THE DISPLAY OF rSO_2 READINGS. ENVIRONMENTS WITH EXCESSIVE AMBIENT LIGHT SUCH AS BRIGHT SUNLIGHT OR STRONG OPERATING ROOM LIGHTING MAY REQUIRE COVERING THE SOMASENSOR WITH AN OPAQUE DRAPE OR BLANKET.

To further assist the operator in eliminating false readings, the INVOS System will not display rSO_2 values or collect data when outside interference is too great.

Removing the Sensor

USE CARE WHEN REMOVING THE SENSOR FROM THE PATIENT. IF DIFFICULT TO REMOVE, USE A COMMERCIAL ADHESIVE SOLVENT TO LOOSEN THE SENSOR AND PEEL BACK SLOWLY TO PREVENT DAMAGE TO THE PATIENT'S SKIN.

Commercially available adhesive solvents include the following:

- Uni-solve, Smith and Nephew in the Netherlands Tel: 31 20 654 3999 or http://www.smith-nephew.com.
- Detachol, Ferndale Laboratories, Inc., Ferndale, Michigan, USA Tel: 248-548-0900 or http://www.ferndalelabs.com.
- 3M Remover Lotion, 3M Health Care in The Netherlands Tel: 011-31-715-450-450 or http://www.3m.com/healthcare/.

Screen Format

The display screen on the INVOS System is composed of several elements. See Figure 6.6 for a detailed guide.

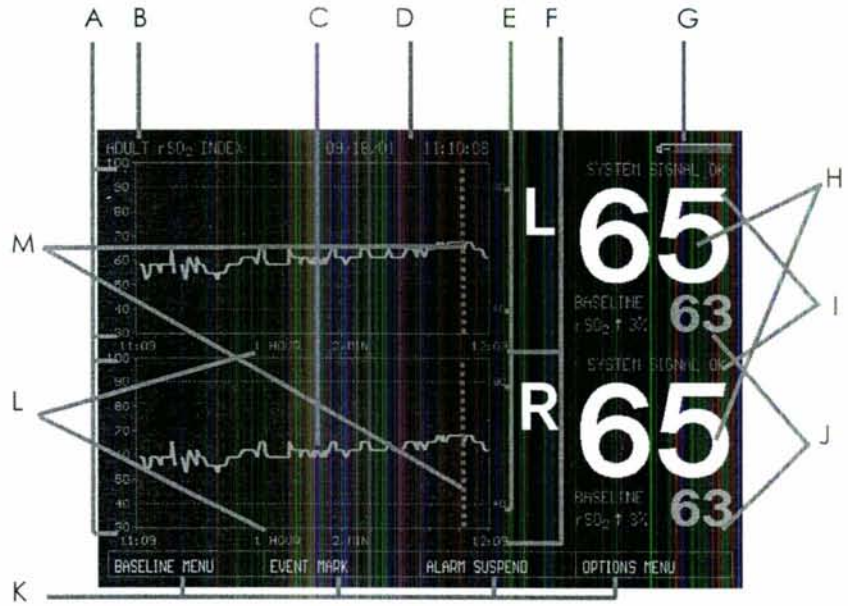


Figure 6.6 Display Screen.

A. Trend (High and Low) Scale (Chapter 7)
B. Adult or Pediatric Indication
C. Trend Data (Chapter 7)
D. Date and Time (Chapter 7)
E. Alarm Limits (Chapter 7)
F. Time Window Scale; variable up to 24 hours (Chapter 7)
G. Battery Powered Status Message (Chapter 6)
H. Digital rSO_2 (%) reading, updated continuously while monitoring
I. Status Messages (Chapter 6)
J. Baseline Status (Chapter 6)
K. Menu Options (Chapter 7)
L. Trending Rate Message Area (Chapter 7)
M. Event Mark

Screen Messages

There are two types of messages that appear on the screen: "Operating Messages" and "Status Messages." These messages are described below.

Operating Messages

ADULT or **PEDIATRIC** - This message will be located in the top left corner of the display screen. It indicates that the INVOS System is in **ADULT** or **PEDIATRIC** mode depending on the model SomaSensor.

PAUSED – The **PAUSED** message will be located in place of the rSO_2 % value. It indicates that the INVOS System is in **PAUSE** mode. The device will not operate or store data in **PAUSE** mode. Push **RUN/PAUSE** to begin monitoring.

Status Messages

During normal monitoring situations one of the following status messages will appear above each rSO_2 value:

SYSTEM SIGNAL OK - Indicates proper connection and functioning of the SomaSensor and the INVOS System. Digital rSO_2 % readings should appear below this message.

ALARM HIGH - This message, along with a bell will appear if the Upper Alarm Limit is exceeded. A tone accompanies the message.

ALARM LOW - This message, along with a bell will appear if the Lower Alarm Limit is exceeded. A tone accompanies the message.

During situations when readings cannot occur, the following status messages may appear:

POOR SIGNAL QUALITY - System is operating but readings will not appear because they are unstable or may be corrupted by a noisy power source or a very weak signal. Try another hospital grade electrical outlet or make sure there is no hair under the sensor. A tone accompanies the message.

EXCESSIVE LIGHT - Indicates the SomaSensor is properly connected to the Preamp but not to the patient or that there is too much outside light. No digital rSO_2 will appear. Check the connection to patient and replace sensor if necessary. If the sensor is properly adhered to the patient, try draping the sensor. A tone accompanies the message.

SENSOR NOT CONNECTED - Indicates the SomaSensor is not connected to the Preamp. No rSO_2 value will appear. Re-attach the sensor to the bilateral reusable cable or check the reusable cable connection to the Preamp. A tone accompanies the message.

REPLACE SENSOR - This message will appear if the INVOS System cannot read calibration data from the SomaSensor. Mixed adult and pediatric sensor types, using pediatric sensors in the adult Model 4100, a defective sensor, or a defective bilateral reusable cable could cause this.

INTERFERENCE DETECTED - There is excessive electromagnetic noise caused by another instrument. Normal operation of the INVOS System will resume when the excessive noise stops.

PREAMP NOT CONNECTED – Indicates the Preamp is not properly connected to the INVOS Cerebral Oximeter. Make sure the Preamp connector is locked into the Cerebral Oximeter front panel. Normal operation of the INVOS System will resume when the Preamp is reconnected.

Additional status message that appears when power is coming from the internal back up battery:

Battery Symbol/Gauge - Appears when the INVOS System is operating on battery power. The symbol fill indicates approximate battery capacity. When the fill inside the battery begins to disappear, the battery is getting closer to depletion. A tone indicates when the unit battery power is critically depleted. No battery symbol appears when the INVOS System is not operating on battery power.

NOTE: REFER TO ERROR STATUS MESSAGES TO TRY TO CORRECT A PROBLEM, SEE CHAPTER 10.

Setting a Baseline

The Baseline Status can be set to display relative rSO_2 changes from baseline. Both decreases and increases from baseline may signify dysfunction and developing pathology. Changes in rSO_2 of 20% from baseline are considered clinically significant and cause for concern. See Frequently Asked Questions, Appendix B, for more information.

When trend data begins to be gathered and patient condition is stable, e.g. for surgical patients, prior to induction, a baseline reading should be obtained. To set the baseline, start by pressing the **BASELINE MENU** key on the **MAIN MENU** below the display screen.

BASELINE MENU	EVENT MARK	ALARM SUSPEND	OPTIONS MENU

Figure 6.7 Main Menu.

Press the **BASELINE MENU** key and the following menu options will appear:

BOTH CHANNELS	SET BASELINE		MAIN MENU

Figure 6.8 Baseline Menu.

The first key from the left toggles between **BOTH CHANNELS**, **RIGHT** or **LEFT** channels. Default is **BOTH CHANNELS**. Choose accordingly.

Press the second key from the left to **SET BASELINE**. The baseline value(s) will be set at the current rSO_2 value(s) and the menu will return to the **MAIN MENU**. Also, a two (2) will be placed in the EVENT MARKER column of the digital output and disk drive output data to signify the time and rSO_2 value at baseline capture. See Chapter 8 for output formats.

Alarms

Alarm messages and tones alert the INVOS System operator of a condition in the patient or the INVOS System requiring attention. Upon alarm, the operator should check the patient's condition first to determine the cause of alarm. Sensor attachment, upper and lower alarm limits, battery capacity, and other messages that may appear on the display should be verified to validate the alarm condition.

Patient Alarm Notification

When the rSO_2 exceeds the upper or lower alarm limits, the INVOS System alerts the operator to this condition. Trend data continues to be gathered.

1. An alarm tone sounds. ***Immediately profile the patient.***
2. A bell appears in the center of the screen.
3. The alarm is non-latching; if the condition passes, the alarm will automatically reset.
    a. To permanently silence the alarm, touch the **ALARM SUSPEND** option from the main display screen. A bell appears for both channels. The following screen appears:

LEFT	RIGHT		MAIN MENU

Figure 6.6 Alarm Suspend Menu.

Press the **MAIN MENU** option key to return to the main menu display screen leaving both channels suspended. Or, press the **LEFT** or **RIGHT** menu option keys to toggle the alarm **ON/OFF** for the individual channel.

b. To activate alarms again when both channels are silenced, touch the **ALARM SUSPEND** option from the main display screen.

   If an individual channel is silenced, touch the **ALARM SUSPEND** option from the main display screen to suspend **BOTH CHANNELS**. Press the **MAIN MENU** option key to return to the main menu display screen.

CAUTION: USING THE ALARM SUSPEND KEY WILL SILENCE THE AUDIBLE ALARMS PERMANENTLY UNTIL RE-ACTIVATED OR THE INVOS SYSTEM IS REBOOTED.

NOTE: TO CHANGE THE ALARM LIMITS, SEE CHAPTER 7.

Battery Capacity Alarm Notification

A Battery/Symbol Gauge  appears in the upper right corner of the display if the INVOS System is operating on battery power. An alarm tone accompanies the depleted Battery/Symbol Gauge  if the battery power is critical.

Event Mark

An Event Mark may be stored in memory and displayed on the screen to mark any significant event. A vertical dashed line will appear on the screen at the current time and a one (1) will appear in the EVENT MARK column of the digital output or disk drive output data. See Chapter 8 for output formats.

To set an Event Mark, press the **EVENT MARK MENU** key on the **MAIN MENU** below the display screen.

BASELINE MENU	EVENT MARK	ALARM SUSPEND	OPTIONS MENU

Figure 6.9 Main Menu.

Chapter 7

Changing the Settings

Chapter Overview

This chapter describes how to change the following settings on the INVOS System:

Alarm Limits

Alarm Volume

Trend Scales (X and Y Axes)

Trending Rate

Date and Time

NOTE: ALL SETTINGS IN THIS CHAPTER ARE STORED IN THE INVOS SYSTEM NON-VOLATILE MEMORY SO THEY WILL REAPPEAR AS THE USER SET THEM WHEN THE INVOS SYSTEM IS REBOOTED.

Changing Alarm Limits

To change either the upper or lower Alarm Limit, start by pressing the **OPTIONS MENU** key below the main display screen.

BASELINE MENU	EVENT MARK	ALARM SUSPEND	OPTIONS MENU

Figure 7.1 Main Menu.

After pressing the **OPTIONS** key. The following menu options will appear:

OUTPUT SELECT	ALARM SETTINGS	TREND SETTINGS	MAIN MENU

Figure 7.2 Options Menu.

Press the **ALARM SETTINGS** key and the following menu options will appear:

ALARM LIMITS	ALARM VOLUME		MAIN MENU

Figure 7.3 Alarm Limits.

Press the **ALARM LIMITS** key and the following menu options will appear:

BOTH CHANNELS	LOWER LIMIT	CHANGE LIMIT	MAIN MENU

Figure 7.4 Change Limits.

The first key from the left toggles between **BOTH CHANNELS**, **RIGHT** or **LEFT** channels. Default is **BOTH CHANNELS**. Choose accordingly.

The second key from the left toggles between **UPPER** or **LOWER** alarm limit. Default is **LOWER LIMIT**. Choose accordingly.

After choosing between channels and **UPPER** or **LOWER** alarm limit, press the key, **CHANGE LIMIT**. The following screen will appear:

BOTH LOWER = 40	INCREASE	DECREASE	PREVIOUS MENU

Figure 7.5 Change Limits.

Use the **INCREASE** and **DECREASE** option keys to adjust the value.

To change another alarm limit, press the **PREVIOUS MENU** option key. Choose another parameter. Original settings will be stored in memory and will remain active until all changes to the alarm limits are completed.

When the value has been updated to the desired level, press the **PREVIOUS MENU** option key. Press the **MAIN MENU** option key to return to the main display screen and activate settings.

Changing Alarm Volume

Press **OPTIONS** key on the main display screen.

Press the **ALARM SETTINGS** key on the Options Menu.

Press the **ALARM VOLUME** key. The following menu options will appear:

VOLUME = MEDIUM	INCREASE	DECREASE	MAIN MENU

Figure 7.6 Alarm Volume.

Adjust the volume by pressing either the **INCREASE** or **DECREASE** keys.

When the **INCREASE** or **DECREASE** keys are pressed, the corresponding alarm volume will increase or decrease to **HIGH** or **LOW**.

When the Alarm Volume has been updated to the desired level, press the **MAIN MENU** option key to return to the main display screen.

Equipment Alarms:

See Chapter 6 for a description of equipment alarms (status messages).

Changing the Trend Scale

Both the X- and Y- axes of the trend display can be adjusted based on patient condition or anticipated length of monitoring.

To begin changing the plotting scales, press the **OPTIONS** key on the main display screen.

Then press **TREND SETTINGS**. The following screen will appear:

Y-AXIS VALUES	X-AXIS HOURS	TRENDING RATE	MAIN MENU

Figure 7.7 Trend Settings.

Y-AXIS VALUES changes the rSO_2 % value.

X-AXIS HOURS represents hours displayed.

rSO_2 Scale

Press **Y-AXIS VALUES** key. The following screen will appear:

BOTH CHANNELS	LOWER LIMIT	CHANGE LIMIT	MAIN MENU

Figure 7.8 Y Axis Settings.

The first key from the left toggles between **BOTH CHANNELS**, **RIGHT** or **LEFT** channels. Default is **BOTH CHANNELS**. Choose accordingly.

The second key from the left toggles between **UPPER** or **LOWER** Y-axis limit. Default is **LOWER LIMIT**. Choose accordingly.

After choosing between channels and **UPPER** or **LOWER** Y-axis limit, press the key, **CHANGE LIMIT**. The following screen will appear:

BOTH LOWER = 30	INCREASE	DECREASE	PREVIOUS MENU

Figure 7.9 Minimum Value.

Using the **INCREASE** and **DECREASE** keys, Adjust the maximum or minimum values.

To change another value, press the **PREVIOUS MENU** option key. Choose another parameter. Changes made to settings are not activated until return to the **MAIN MENU**.

When the value has been updated to the desired level, press the **PREVIOUS MENU** option key. Press the **MAIN MENU** option key to return to the main display screen and activate settings.

NOTE: THE MAXIMUM AND MINIMUM Y-AXIS VALUES CANNOT BE ADJUSTED PAST THE CURRENTLY SELECTED ALARM LIMIT RANGE. IT MAY BE NECESSARY TO ADJUST THE ALARM LIMITS FIRST IN ORDER TO SELECT THE DESIRED SCALE (CHAPTER 7).

Time Scale

To adjust the time scale, press the **OPTIONS key** on the main screen display.

Then press the third key from the left, **TREND SETTINGS**.

Press **X-AXIS HOURS**. The following screen will appear:

X-AXIS HOURS = 2	INCREASE	DECREASE	PREVIOUS MENU

Figure 7.10 X-Axis Settings.

Use the **INCREASE** and **DECREASE** menu option keys to change the hours viewed. When trend rate is set for 1/minute, the view options are 2, 4, 8, 12 and 24 hours. When trend rate is set for 2/minute, the view options are 1, 2, 4, 8, and 12 hours.

To change another value, press the **PREVIOUS MENU** option key. Choose another parameter. Changes made to settings are not activated until return to the **MAIN MENU**.

When the value has been updated to the desired level, press the **PREVIOUS MENU** option key. Press the **MAIN MENU** option key to return to the main display screen and activate settings.

Changing the Trending Rate

The INVOS system can trend up to 24 hours and store up to 1440 data points in memory. This corresponds to one point per minute for 24 hours or one point every 30 seconds for 12 hours, user selectable. The selected trending rate will be displayed just below the trend display.

To Change Trending Rate, press the **OPTIONS MENU** key from the main display screen.

Press the third key from the left, **TREND SETTINGS**. The following screen will appear:

Y-AXIS VALUES	X-AXIS HOURS	TRENDING RATE	MAIN MENU

Figure 7.11 System Setup Settings.

Press **TRENDING RATE**. The following screen will appear:

1 PER MINUTE	2 PER MINUTE		PREVIOUS MENU

Figure 7.12 Trending Rate.

Trending Rate options are 1 or 2 per minute. Touch the key below the option you choose. This will activate the new trending rate and return to the main display screen.

NOTE: IF 12 OR MORE HOURS OF DATA ARE ALREADY STORED, THE TREND RATE WILL NOT CHANGE FROM 1 PER MINUTE TO 2 PER MINUTE.

Changing Time Setting

After you turn the INVOS System **ON**, the unit will sequence through a series of start-up and self-test screens and will stop at a **NEW PATIENT/PREVIOUS PATIENT** screen. To change the time from this screen:

Press the third key from the left, **DATE/TIME**. The following screen will be displayed:

DATE	TIME		MAIN MENU

Figure 7.13 System Setup.

Press **TIME** option key. The following screen will appear:

HOURS = 14	INCREASE	DECREASE	PREVIOUS MENU

Figure 7.14 Time Setting.

Toggle the first option key to select **HOURS, MINUTES** or **SECONDS**. Use the **INCREASE** or **DECREASE** option keys to change the time.

When the time has been updated, press the **PREVIOUS MENU** option key to return to the **NEW PATIENT/PREVIOUS PATIENT** display screen and activate settings.

Changing Date Setting

After you turn the INVOS System **ON**, the unit will sequence through a series of start-up and self-test screens and will stop at a **NEW PATIENT/PREVIOUS PATIENT** screen. To change the date from this screen:

Press the third key from the left, **DATE/TIME**. The following screen will be displayed:

DATE	TIME		MAIN MENU

Figure 7.15 Date/Time Menu.

Press **DATE** option key. The following screen will appear:

DAY= 26	INCREASE	DECREASE	PREVIOUS MENU

Figure 7.16 Date Setting.

Toggle the first option key to select **DAY**, **MONTH** or **YEAR**. Use the **INCREASE** or **DECREASE** option keys to change the date.

When the date has been updated, press the **PREVIOUS MENU** option key to return to the **NEW PATIENT/PREVIOUS PATIENT** display screen.

Chapter 8

Storing, Printing, Outputting and Reviewing

Chapter Overview

This chapter addresses the optional disk drive, describes how to perform printing and digital outputting functions and activate review mode.

WARNING: ACCESSORIES NOT SUPPLIED BY SOMANETICS MAY NOT MEET EN60601-1-2 (IEC 601-1-2) STANDARDS. CONTACT SOMANETICS' CUSTOMER SERVICE DEPARTMENT AT (248) 689-3050, EXT. 255, VIA FAX AT (248) 689-4272 OR VIA EMAIL AT customerservice@somanetics.com FOR COMPATIBLE PRODUCTS THAT MAY MEET THESE REQUIREMENTS.

Printing Data

NOTE: ONLY A SOMANETICS SUPPLIED PRINTER SHOULD BE USED WITH THE INVOS CEREBRAL OXIMETER. NO OTHER PRINT DEVICES SHOULD BE CONNECTED TO THE CEREBRAL OXIMETER. FOR ADDITIONAL INFORMATION ON ACQUIRING AND USING A PRINTER, CONTACT SOMANETICS CUSTOMER SERVICE AT (248) 689-3050, EXT. 255, VIA THE INTERNET AT http:// www.somanetics.com OR VIA EMAIL AT customerservice@somanetics.com.

The printer output allows data from the INVOS System to be transferred to paper. This port is a standard centronics parallel output. The printer communication protocol is designed to support the INVOS Thermal Printer available from Somanetics.

Data can be stored in real time up to 12 or 24 hours depending on the user selectable **TRENDING RATE** and printed after the fact. Data collected previous to the 12 or 24-hour periods will not be stored.

The time required for all trended data to be printed in Case History mode depends on the printer that is being used. The INVOS Thermal Printer print time is approximately 60:00 minutes for 24 hours of data.

If the printer is operated in Real-Time mode, the printer report will be complete at the end of the case.

Setup/Installation

1. Place the unit on a flat surface where it is protected against falling.
2. Attach the printer cable to the printer and the connector labeled **PRINTER** on the back panel of the INVOS Cerebral Oximeter. Connect the power cord to the printer and plug the AC adapter into an AC outlet.
3. Turn on the printer and make sure that it is on line.

Printing Data in Real Time

1. Press the **OPTIONS MENU** key on the main display screen.
2. Press **OUTPUT SELECT** from the Options Menu. The following menu will appear:

PRINTER	DISK DRIVE	DIGITAL OUTPUT	REVIEW

Figure 8.1 Output Options.

3. Press the **PRINTER** option key. The following menu will appear:

TURN PRINTER ON	CASE HISTORY		MAIN MENU

Figure 8.2 Real Time Data or Stored Data Option.

4. Press **TURN PRINTER ON** to enable real time printing. At completion of the case, toggle the first option key **TURN PRINTER OFF** to disable real time printing.

Printing Stored Data

1. Press the **OPTIONS MENU** key on the main display screen.
2. Press **OUTPUT SELECT** from the Options Menu. The following menu will appear:

PRINTER	DISK DRIVE	DIGITAL OUTPUT	REVIEW

Figure 8.3 Output Options.

3. Press the **PRINTER** option key. The following menu will appear:

TURN PRINTER ON	CASE HISTORY		MAIN MENU

Figure 8.4 Real Time Data or Stored Data Option.

4. Press **CASE HISTORY** to enable stored data printing. If real-time printing is on, it will be automatically shut off. Toggle the second option key **PRINT CANCEL** to cancel printing of stored data.

Disk Drive Operation

NOTE: ONLY A SOMANETICS SUPPLIED DISK DRIVE SHOULD BE USED WITH THE INVOS CEREBRAL OXIMETER. NO OTHER DISK DRIVE DEVICES SHOULD BE CONNECTED TO THE CEREBRAL OXIMETER. FOR ADDITIONAL INFORMATION ON ACQUIRING AND USING A DISK DRIVE UNIT, CONTACT SOMANETICS' CUSTOMER SERVICE DEPARTMENT AT (248) 689-3050, EXT. 255, VIA THE INTERNET AT http::://www.somanetics.com OR VIA EMAIL AT customerservice@somanetics.com.

WARNING: DO NOT REMOVE OR INSERT A DISK WHEN THE DISK ACCESS LIGHT IS ILLUMINATED. DAMAGE TO THE DISK OR THE DRIVE COULD RESULT.

The disk drive port allows data from the INVOS System to be transferred to an IBM formatted DS/HD 3.5" floppy disk. The communication protocol is designed to support the INVOS Disk Drive available from Somanetics.

The disk drive duplicates the storage function available in the INVOS System with the exceptions that it offers greater capacity, selectable storage rates and stores on a nonvolatile medium suitable for archiving. The disk drive allows rSO_2 readings to be stored for future review and archiving. It supports the following features and functions:

- Storage capacity of 1 to 6 days depending on storage rate selected
- Four different storage rates
- Non-volatile medium suitable for archiving
- Stored data can be plotted in a variety of formats

Setup/Installation

1. Place the unit on a flat surface where it is protected against falling.
2. Attach the disk drive cable to the connector labeled **DISK DRIVE** on the back panel of the INVOS Oximeter. Power to the Disk Drive is derived from the INVOS System.
3. Insert a blank formatted disk into the disk slot. Use only IBM formatted DS/HD 3.5" Floppy Disks (1.44Mb).
4. If there is a previous case stored on the disk (not blank), the new data will be appended to the end of the older file. The 2 cases can be separated after the fact using date and time to identify the break point.

Storing Data In Real-Time to the Disk Drive

1. Press the **OPTIONS MENU** key on the main display screen.
2. Press **OUTPUT SELECT** from the Options Menu. The following menu will appear:

PRINTER	DISK DRIVE	DIGITAL OUTPUT	REVIEW

Figure 8.5 Output Options.

3. Press the **DISK DRIVE** option key. The following menu will appear:

TURN DISK ON	CASE HISTORY		MAIN MENU

Figure 8.6 Real Time Data or Stored Data Option.

4. Press **TURN DISK ON** to enable real time data storage. The following menu will appear:

EVERY 10 SECONDS	EVERY 20 SECONDS	EVERY 30 SECONDS	EVERY 60 SECONDS

Figure 8.7 Data Storage Rate Option.

5. Choose the desired storage rate; the disk drive will begin to store data at the appropriate intervals.

INVOS System Setting	Capacity
Every 10 seconds	1 Day
Every 20 seconds	2 Days
Every 30 seconds	3 Days
Every 60 seconds	6 Days

Figure 8.8 Data Storage Capacity.

*NOTE: IF THE **DISK DRIVE** IS TURNED ON WHEN THE DISK DRIVE IS NOT ATTACHED OR A DISKETTE IS NOT IN THE DRIVE A DISK ERROR MESSAGE WILL APPEAR ON THE OXIMETER SCREEN.*

6. Toggle the first option key **TURN DISK OFF** to disable real time storage before removing the diskette.

Data can be stored in real time indefinitely.

The stored data can be accessed on any IBM or compatible personal computer using a common spreadsheet program like Lotus 1-2-3 or Microsoft Excel. The file will be named **DATA.DAT** and will be stored in a space delimited ASCII text file in the data format given below:

Date	Time	Left	rSO2	Event Marker	Status	A	B	C	D	Right	rSO2	Event Marker	Status	A	B	C	D	Lot #	Serial #	Lot #	Serial #

Figure 8.9 ASCII text file data format.

It is necessary to parse the data when entering it into a spreadsheet. Follow the software supplier's directions to proceed.

Sending Stored Data to the Disk Drive

1. Press the **OPTIONS MENU** key on the main display screen.
2. Press **OUTPUT SELECT** from the Options Menu. The following menu will appear:

PRINTER	DISK DRIVE	DIGITAL OUTPUT	REVIEW

Figure 8.10 Output Options.

3. Press the **DISK DRIVE** option key. The following menu will appear:

TURN DISK ON	CASE HISTORY		MAIN MENU

Figure 8.11 Real Time Data or Stored Data Option.

4. Press **CASE HISTORY** to send stored data to the Disk Drive. If real-time disk storage is on, it will be automatically shut off. The data will output until complete. The time required is short; there is no cancel option.

Up to 24 hours of data may be stored after the fact. Data collected previous to the 12 hour (@ 2/min. trending rate) or 24 hour (@ 1/min. trending rate) periods will not be stored.

While outputting stored data, monitoring will cease and the INVOS System will display the last rSO_2 value measured before the output started. Monitoring will resume when the outputting function is complete.

Case history data can be accessed on any IBM or compatible personal computer using a common spreadsheet program like Lotus 1-2-3 or Microsoft Excel. The file will be named **HIST.DAT** and will be stored in a space delimited ASCII text file in the data format given below:

Date	Time	Left	rSO2	Event Marker	N/A	Right	rSO2	Event Marker	N/A

Figure 8.12 ASCII text file data format.

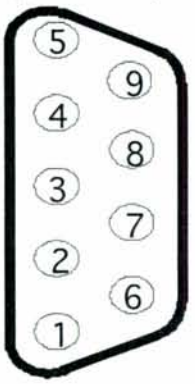
It is necessary to parse the data when entering it into a spreadsheet. Follow the software supplier's directions to proceed.

Digital Output Port

WARNING: ALL EQUIPMENT USED WITHIN TWO (2) METERS OF THE PATIENT (PATIENT ENVIRONMENT) MUST BE IEC-601 APPROVED. ALL EQUIPMENT USED OUTSIDE THE PATIENT ENVIRONMENT MUST BE APPROVED TO THE APPROPRIATE IEC OR ISO STANDARDS (E.G.: IEC950 FOR OFFICE EQUIPMENT).

This port provides real time and stored digital data communications with other devices such as a personal computer (PC). Data is outputted during every screen update, approximately every 5-6 seconds by connecting the INVOS System to a receiving device via a 9-pin to 9-pin serial null modem cable. It can also send all stored data to the receiving device. Figure 8.12 shows pin out information for the digital output connector. Consult Somanetics for compatibility with other commercial devices or to order the Null Modem Cable

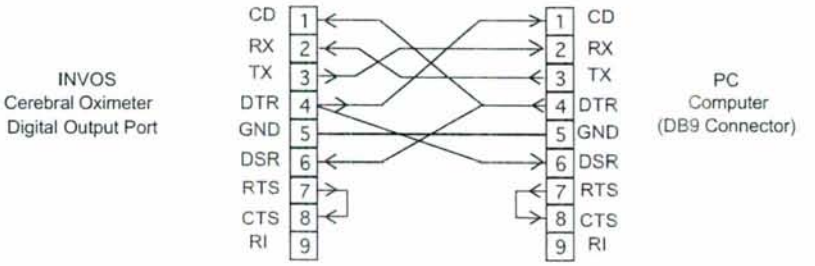
Digital Output Port Back Panel Connection



Pin #	Description
1	Data Carrier Detect
2	Receive Data
3	Transmit Data
4	Data Terminal Ready
5	Ground
6	Data Set Ready
7	Request to Send
8	Clear to Send
9	Ring Indicator

Figure 8.13 Digital Output Port.

The Digital Output Port can be attached to a variety of external serial devices, such as a serial printer, modem or computer terminal. Figure 8.13 shows two cable diagrams for connecting the INVOS System to external devices.



OR

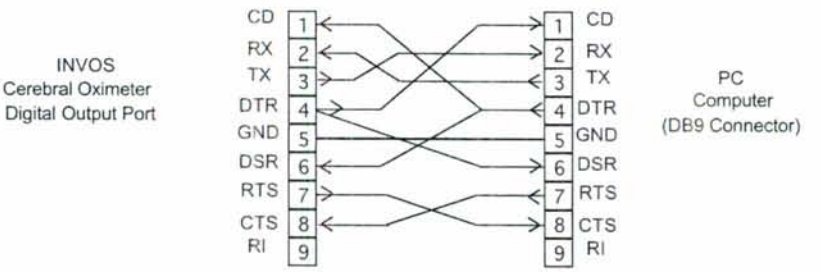


Figure 8.14 Cable Diagram for Connection to Digital Output Port by a "Null Modem" Cable

The digital communications output uses the following protocol:

- 9600 Baud
- No Parity
- 8 Data Bits
- 1 Stop Bit

During real time outputting, the data is transmitted asynchronously using no hand-shaking approximately every 5-6 seconds in an ASCII character string. The Digital Output Port also allows stored data from the INVOS System to be transferred to other devices.

Setup/Receiving Digital Data on a PC

Storing INVOS System Data using a Portable Computer (PC) with Windows 95 or later can be completed by obtaining the equipment listed and the instructions following to complete initial computer set-up:

- A PC with Windows Operating System and Hyper Terminal Program.
- A compatible spread sheet program that can import text files, such as Microsoft Excel or Lotus
- A Null Modem Cable, Somanetics' Model #DB9DB9

Using Hyper Terminal

1. In Windows, select or click "Start," "Programs," "Accessories," "Communications," (if necessary) and "Hyper Terminal"
2. Double-Click on "Hyper Terminal" icon.
3. In the window "Connection Description," under Name: Enter "INVOS" and select an icon.
4. In the window "Phone Number" under Connect using: Select "Direct to Com 1 (or 2)." Click "OK"
5. In the window "COM1 Properties" Enter the following:
6. Bits per second 9600 Baud
7. Data bits 8
8. Parity None
9. Stop bits 1
10. Flow Control Hardware
11. Click "OK"
12. Under "File, select "Save" and "Exit" (When prompted to disconnect, Click "Yes"). Now when Hyper Terminal is selected, an icon for INVOS will be displayed. Double-clicking this icon will automatically restore all entered properties.

NOTE: THE INVOS ICON CAN BE DRAGGED TO THE DESKTOP WHERE IT WILL BE EASY TO ACCESS

To Collect Data

1. Make sure a **null modem cable** is connected to the COM 1 (or 2) port on the computer and the "1010" port on the back of the INVOS Oximeter.
2. Power up both the computer and the INVOS System.
3. On the computer, click **"Start" "Programs" "Accessories" "Hyper Terminal"** and double-click **INVOS**
   Or, if **INVOS** terminal icon is on the desktop, double-click it.
4. To save data: Select **"Transfer" "Capture Text"**
   In the "Capture Text" window, enter the file name and directory in which you wish to save the file. Click "Start."

5. Allow the **INVOS System** to calibrate the SomaSensor and begin monitoring. Data will begin to transfer to the PC.
6. See instructions below for Case History data collection mode.
7. When monitoring is complete: Select **"Call," "disconnect,"** and close the **INVOS** window.

Data can be stored in real time indefinitely.

The data can be accessed using a common spreadsheet program like Lotus 1-2-3 or Microsoft Excel. The file will be stored as a space delimited ASCII text file in the data format given below:

Date	Time	Left	rSO2	Event Marker	Status	A	B	C	D	Right	rSO2	Event Marker	Status	A	B	C	D	Lot #	Serial #	Lot #	Serial #

Figure 8.15 ASCII text file data format.

It is necessary to parse the data when entering it into a spreadsheet. Follow the software supplier's directions to proceed.

Graph rSO_2 vs. Time with Microsoft Excel

1. Open Excel program. Under **"File," "Open,"** select file name and directory from above (make sure "all files" or "text files" is selected). Excel will display the Text Import Wizard dialog box.
2. Under Original Data Type select **"Delimited,"** remove **"Tab"** and select **"Space."**. The data should now be parsed into individual cells.
3. Insert an empty row at the top of the data by selecting **"Row"** from the **"Insert"** menu. Enter column headings in row 1. The data format and column headings are displayed in Figure 8.15.
4. Press **CTRL** on the keyboard and select or highlight the time column starting from row 1 to the end of the data. Without releasing the CTRL key, select or highlight the left and right rSO_2 data columns from row 1 to the end of the data.
5. Select the "Chart" icon  in the tool bar or select **"Chart"** from the **"Insert"** menu. The Chart Wizard will appear.
6. Choose Chart Type by selecting **"XY Scatter"** as the Chart type and **"Scatter with data points connected by smooth lines"** as the Chart sub-type. Other Chart sub-types may be chosen for different graph line formats. Select **"Next."**

NOTE: USING THE "XY SCATTER" INSTEAD OF "LINE" WILL YIELD A TRUE X-AXIS TIME SCALE.

7. Chart Source Data with the data range and columns previously selected in step 4. Select **"Next."**
8. Enter Chart Options, such as **"Chart title," "Value (X) axis"** and **"Value (Y) axis."** Other parameters may also be entered, if desired. After completing all of the Chart Options, select **"Next."**
9. Select **"Finish"** and save the file as an Excel Workbook.

To further format the graph, you may now double click on either axes and a dialogue box will appear to allow changes to font, scale, alignment, etc.

Outputting Stored Data

1. Press the **OPTIONS MENU** key on the main display screen.

2. Press **OUTPUT SELECT** from the Options Menu. The following menu will appear:

PRINTER	DISK DRIVE	DIGITAL OUTPUT	REVIEW

Figure 8.16 Output Options.

3. Press the **DIGITAL OUTPUT** option key. The following menu will appear:

CASE HISTORY			MAIN MENU

Figure 8.17 Stored Data Option.

4. Press **CASE HISTORY** to send stored data to the Digital Output Port. Real-time output will be shut off and resume when the Case History output is complete. The data will output until complete. The time required is brief, there is no cancel option.

Up to 24 hours of data may be outputted after the fact. Data collected previous to the 12 hour (@ 2/min. trending rate) or 24 hour (@ 1/min. trending rate) periods will not be stored.

While outputting stored data, monitoring will cease and the INVOS System will display the last rSO_2 value measured before the output started. Monitoring will resume when the outputting function is complete.

The stored data can be accessed on any IBM or compatible personal computer using a common spreadsheet program like Lotus 1-2-3 or Microsoft Excel. The file will be stored as an ASCII text file in the data format given below:

Date	Time	Left	rSO2	Event Marker	N/A	Right	rSO2	Event Marker	N/A

Figure 8.18 ASCII text file data format.

It is necessary to parse the data when entering it into a spreadsheet. Follow the software supplier's directions to proceed.

Status Codes for Disk Drive and Digital Output

Status codes appear in the data shown above for real-time disk drive and digital outputs. These codes correspond to status messages that appear above the rSO_2 % value on the display screen as follows:

CODE	STATUS MESSAGE	ACTION
1	Sensor Not Connected	Check sensor connection. Check Reusable Cable connection at Preamp.
2	Excessive Light	Check sensor adhesion. Drape sensor. Reduce room light.
3	Poor Signal Quality	Check sensor connection for fluid contamination. Remove hair under sensor. Use another medical-grade electrical outlet.
4	System Signal OK	System operating normally.
5	Alarm High	Profile patient.
6	Alarm Low	Profile patient.
7	Blank	None.
8	N/A	
9	Battery Low	Check mains power switch on Back Panel. Connect to AC Line.
10	Pause Mode	Press RUN/PAUSE key.

CODE	STATUS MESSAGE	ACTION
11	Preamp Not Connected	Check Preamp connection at monitor. Replace Preamp.
12	Com Port Unavailable	Check connections with Com Port device (PC).
13	Printer Unavailable	Check connections with Printer.
14	Disk Error	Check connections with Disk Drive.
15	N/A	
16	N/A	
17	Replace Sensor	Check for correct sensor type. Connect new sensor. Replace Reusable Cable.
18	N/A	
19	Interference Detected	Noise corrupting rSO_2 data (electrocautery). Move or turn off source of interference.
20	Disk Full	Replace disk.

Figure 8.19 Status Codes for Disk Drive and Digital Output.

Review Mode

The review mode allows review of 12 hours (@ 2/min. trending rate) or 24 hours (@ 1/min. trending rate) of stored data trends on the INVOS Oximeter screen. It reviews in one or two hour increments in a page format.

Access Review Mode

Press the **OPTIONS MENU** key on the main display screen.

Press **OUTPUT SELECT** from the Options Menu. The following menu will appear:

PRINTER	DISK DRIVE	DIGITAL OUTPUT	REVIEW

Figure 8.20 Output Options.

Press the **REVIEW** option key. The following menu will appear:

←	→		MAIN MENU

Figure 8.21 Review Mode.

NOTE: MORE THAN ONE (1) HOUR OF DATA (2/MIN STORAGE RATE) MUST BE STORED TO ACTIVATE REVIEW MODE. DATA CAN ONLY BE REVIEWED IN ONE (1) HOUR OR TWO (2) HOUR INCREMENTS DEPENDING ON STORAGE RATE.

Use the ← option key and the → option key to scroll trend lines across the INVOS Oximeter screen in the Review Mode.

When you have completed reviewing, press the **MAIN MENU** option key to return to the main display screen.

Chapter 9

Warranty Information

Chapter Overview

This Chapter details the INVOS Cerebral Oximeter Warranty.

INVOS Cerebral Oximeter Warranty

Key Points

The INVOS System is warranted free of defects for one year from date of delivery to the customer.

Warranty repairs can be obtained by calling Somanetics' Customer Service Department.

All returned merchandise shipments must be prepaid and have a Return Materials Authorization (RMA) number.

Certain software and/or hardware upgrades may be provided free of charge during the warranty period when units are returned to Somanetics.

Unauthorized repairs, misuse or abuse of the device will void the warranty.

CAUTION: DO NOT ATTEMPT TO PERFORM ANY SERVICE OR TAMPER WITH THE WARRANTY SEAL UNLESS YOU HAVE BEEN AUTHORIZED IN WRITING BY SOMANETICS. REPAIRS MADE BY ANYONE NOT AUTHORIZED BY SOMANETICS DURING THE WARRANTY PERIOD WILL VOID THE PRODUCT WARRANTY.

Limited Warranty and Disclaimer

Somanetics warrants the Products to be free of defects in material or workmanship resulting in the Products failing to meet Somanetics' published specifications at the time of delivery. Claims may be made under this warranty only in the event of failure due to such defect within one year of delivery. Somanetics' sole and exclusive obligation (customer's sole and exclusive remedy) with respect to this warranty shall be to repair or, at Somanetics' sole discretion, replace products which prove to be defective in material and workmanship resulting in the products failing to meet Somanetics' published specifications during the one-year warranty period from delivery to the customer, provided they are returned to Somanetics, prepaid.

CUSTOMER'S SOLE AND EXCLUSIVE REMEDY FOR SOMANETICS' LIABILITY OF ANY KIND, INCLUDING, WITHOUT LIMITATION, NEGLIGENCE, WITH RESPECT TO ANY ITEM FURNISHED UNDER THIS AGREEMENT, SHALL BE LIMITED TO THE REMEDY PROVIDED IN THE PRECEDING SENTENCE. NO OTHER WARRANTY OR REMEDY IS EXPRESSED OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ANY WARRANTY IMPLIED BY CUSTOM OF TRADE OR COURSE OF DEALING, OR ANY WARRANTY AGAINST HIDDEN DEFECTS. NO REPRESENTATIONS CONCERNING THE PRODUCTS ARE OR WERE MADE OR RELIED UPON WITH RESPECT TO THE QUALITY OR FITNESS

OF THE PRODUCTS. DISTRIBUTOR AND ITS ULTIMATE CUSTOMERS WAIVE THE RIGHT TO ANY CLAIMS BASED ON AN ALLEGED BREACH OF WARRANTY BY SOMANETICS EXCEPT AS OTHERWISE PROVIDED IN THIS AGREEMENT.

Customer shall immediately notify Somanetics of any claims under any of the foregoing warranties. All of the Products are warranted to Distributor and its ultimate customers, as set forth herein, and to no other persons. Somanetics and Designees, may alter, modify or deviate from this warranty with respect to any Products sold to Customer after Customer receives written notice of the revised warranty. This Limited Warranty specifically excludes disposable sensors, accessory items and fuses.

Warranty Labor

If Somanetics determines that the Product is defective and that the claim was made within the warranty period, Somanetics shall satisfy its obligations under this warranty by repairing or replacing the Product and returning it to Customer, within the parameters established above, at Somanetics' expense. If Somanetics determines that the Product is not defective or that the claim was not made within the warranty period, Somanetics will return the Product to Customer and charge the Customer for shipping, handling and diagnostic fees specified in the Somanetics Terms and Conditions of Sale.

Disclaimer of Consequential Damages

SOMANETICS' LIABILITY OF ANY LOSSES, DAMAGES OR EXPENSES OF ANY KIND WHICH ARISE OUT OF, OR WHICH ARE IN CONNECTION WITH, THE PRODUCTS COVERED BY THE WARRANTY SET FORTH HEREIN OR THEIR DESIGN, MANUFACTURE OR SALE, WHETHER THE CLAIM IS IN CONTRACT, TORT OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, LIABILITY FOR BREACH OF THE WARRANTY PROVIDED HEREIN, IS LIMITED, UNLESS OTHERWISE PROHIBITED BY LAW, TO AN AMOUNT NOT EXCEEDING THE COST OF PERFORMING THE OBLIGATIONS CONTAINED IN THE WARRANTY ACCORDING TO ITS TERMS, AND IN NO EVENT SHALL SOMANETICS' LIABILITY EXCEED THE VALUE OF THE PRODUCT GIVING RISE TO SUCH LIABILITY. UNDER NO CIRCUMSTANCES SHALL SOMANETICS BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING, WITHOUT LIMITATION, LOSS, DAMAGE, OR EXPENSE ATTRIBUTABLE TO A LOSS OF USE OF THE PRODUCT, A LOSS OR DAMAGE TO PROPERTY OTHER THAN THE PRODUCT, A LOSS OF EXPECTED INCOME, LOSS FROM BUSINESS DISRUPTION, OR OTHER COMMERCIAL LOSS, DUE TO ANY CAUSE, EVEN IF SOMANETICS HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, IN CONNECTION WITH THIS AGREEMENT, THE PRODUCTS, OR ANY USE OF THE PRODUCTS (EXCEPT FOR LIABILITY FOR CONSEQUENTIAL DAMAGES WHICH BY LAW MAY NOT BE DISCLAIMED).

Failure of Product

Somanetics shall not be responsible for failure of Products, and the warranty provided herein will not apply if such failure is attributable to accident (including, without limitation, damage during shipment), neglect, misuse, abuse or exposure of the Products to conditions beyond the environmental and operating constraints specified by Somanetics.

Purpose of Product

This Limited Warranty is given on the basis that Somanetics INVOS System is designed and intended solely for the purpose of providing patients and physicians with information concerning regional oxygen changes in the brain. Accordingly, Somanetics makes no claim or warranty, express or implied, related to the use of Somanetics INVOS System as a test for a patient's overall condition or any specific disease.

Returning a Unit for Service

When returning an INVOS System, ship it prepaid in the original container as received, if possible. **It is important to use the original container and packing material to prevent damage to the unit in shipping**. Somanetics will not assume responsibility for damage caused in shipment if the customer does not use original shipping materials. Shipping materials can be obtained by contacting Somanetics' Customer Service Department. Call and request a Return Materials Authorization (RMA) number from Somanetics' Customer Service Department before shipping. Include the following with the shipment:

- Detailed description of the problem or need
- RMA number and serial number of the unit on outside of the box
- Name and phone number of the person to contact within your facility
- Information regarding where and to whom to address the return of the INVOS System
- All accessories that came with the product: Preamp, Bilateral Reusable Sensor Cable, AC Line Cord, and any other optional attachments.

Warnings about Unauthorized Repair

Performing unauthorized service or repairs not described in this manual on any Somanetics INVOS System will void the product's warranty.

NOTE: IF THE UNIT IN QUESTION IS UNDER WARRANTY, YOU SHOULD NOT ATTEMPT TO REPAIR THE UNIT BUT SHOULD RETURN IT TO SOMANETICS CORPORATION FOR REPAIR (SEE WHO TO CONTACT FOR AUTHORIZED REPAIR). REPAIRS MADE BY ANYONE NOT AUTHORIZED BY SOMANETICS DURING THE WARRANTY PERIOD WILL VOID THE PRODUCT WARRANTY.

Who to Contact for Authorized Repair

For authorized repair of a Somanetics INVOS System, contact:

Customer Service Department
Somanetics Corporation
1653 East Maple Road
Troy, MI 48083-4208
Phone: (248) 689-3050, *ext.* 255
Fax: (248) 689-4272
Email: customerservice@somanetics.com
Website: http://www.somanetics.com

Chapter 10

Maintenance

Chapter Overview

!WARNING!

ELECTRIC SHOCK HAZARD!

BEFORE PERFORMING ANY SERVICE, TURN OFF UNIT, THEN DISCONNECT AC POWER (See Figure 5.4 for location) REMOVE THE ENCLOSURE, AND DISCONNECT THE BATTERY CABLE FROM THE DIB BOARD.

Electrostatic Discharge (ESD) protection also is required before performing any service on the unit.

MAKE SURE ALL CABLES ARE CONNECTED AND ALL COMPONENTS ARE INSTALLED CORRECTLY BEFORE ATTEMPTING TO APPLY POWER OR TURN ON THE UNIT.

!!CAUTION!!

Do not attempt to perform any service or tamper with the warranty seal unless you have been authorized in writing by Somanetics. Repairs made by anyone not authorized by Somanetics during the warranty period will void the product warranty.

Maintenance

Chapter Overview

This chapter defines the product in terms of functional units and replaceable parts. It includes a block diagram for clarity.

NOTE: THE INVOS SYSTEM IS CALIBRATED DURING MANUFACTURING AND DOES NOT REQUIRE ADDITIONAL ADJUSTMENTS. THE SOMASENSOR ALSO IS CALIBRATED DURING MANUFACTURING. A SELF-CONTAINED SENSOR ID NUMBER IN THE SOMASENSOR CALIBRATES THE INDIVIDUAL SENSOR TO THE INVOS SYSTEM. ADDITIONAL CALIBRATION IS NOT REQUIRED.

Software Upgrades

Software upgrades are performed using the optional Disk Drive. To inquire about software upgrades contact Somanetics' Customer Service Department at (248) 689-3050, ext. 255 or consult Somanetics' website at http://www.somanetics.com.

Repair Policy

Have all repairs performed by Somanetics authorized repair personnel.

Cleaning

Cleaning the INVOS System

CAUTION: ELECTRICAL SHOCK WARNING. DISCONNECT THE INVOS SYSTEM FROM THE AC POWER BEFORE CLEANING.

WARNING:

DO NOT AUTOCLAVE THE INVOS SYSTEM.

DO NOT GAS STERILIZE THE INVOS SYSTEM.

DO NOT IMMERSE THE INVOS SYSTEM IN ANY LIQUIDS.

1. Disconnect AC Power from the unit. Turn power off.
2. Clean the outside surface of the enclosure with a cloth dampened with Isopropyl alcohol - 70% or mild soap and water solution.
3. Clean the faceplate and screen with a clean, soft cloth and isopropyl alcohol or commercial glass cleaner. **Do not use acetone or abrasives.**
4. If necessary, the INVOS System and cables can be wiped clean with commercial germicidal agents.
5. Allow unit to completely dry before reconnecting AC Power.

Cleaning the Printer

CAUTION: ELECTRICAL SHOCK WARNING. DISCONNECT THE PRINTER FROM THE INVOS SYSTEM BEFORE CLEANING.

CAUTION: DO NOT REMOVE THE COVER. THERE ARE NO USER SERVICEABLE PARTS INSIDE THE PRINTER.

WARNING:

DO NOT AUTOCLAVE THE PRINTER.

DO NOT GAS STERILIZE THE PRINTER.

DO NOT IMMERSE THE PRINTER IN ANY LIQUIDS.

1. Disconnect AC Power from the printer. Turn power off.
2. Clean the printer cabinet with a cloth dampened with Isopropyl alcohol - 70% or mild soap and water solution.
3. Allow the printer to dry before using it.

4. If necessary, the printer and cable can be wiped clean with commercial germicidal agents.

Cleaning the Disk Drive

CAUTION: ELECTRICAL SHOCK WARNING. DISCONNECT THE DISK DRIVE FROM THE INVOS SYSTEM BEFORE CLEANING.

WARNING:

DO NOT AUTOCLAVE THE DISK DRIVE.

DO NOT GAS STERILIZE THE DISK DRIVE.

DO NOT IMMERSE THE DISK DRIVE IN ANY LIQUIDS.

1. Clean the disk drive cabinet with a dampened cloth (Isopropyl alcohol - 70% or mild soap and water solution).
2. Allow the disk drive to dry before using it.
3. If necessary, the disk drive and cable can be wiped clean with commercial germicidal agents.

Have all repairs performed by Somanetics authorized repair personnel.

Care of the SomaSensor

Although the SomaSensor is a non-sterile, disposable item, it should be treated with proper care to prevent damage or data corruption.

To remove the sensor from the Bilateral Reusable Sensor Cable, grip both SomaSensor and cable connectors while pulling out. **Do not pull on any cables.**

Avoid straining or twisting the Bilateral Reusable Sensor Cable.

Remove the protective backing from the adhesive side of the sensor only when the sensor is ready to apply to the patient.

Battery Recharge

WARNING: BATTERY BACKUP IS NOT USER REPLACEABLE.

The battery charges itself while the INVOS System is connected to AC power. It acts as a backup for data storage, power outages, and patient transport. The battery operation time without AC power is approximately 2 hours, starting from a fully charged condition. Recharging time is 15 hours from a full discharge.

NOTE: UPON INITIAL UNPACKING THE BATTERY MAY BE PARTIALLY DISCHARGED. BEFORE ATTEMPTING BATTERY OPERATION, THE BATTERY MUST BE CHARGED BY CONNECTING THE UNIT TO AC POWER IN EITHER OPERATIONAL OR NON-OPERATIONAL MODE. A CHARGE TIME OF 15 HOURS IS REQUIRED TO RECHARGE A DISCHARGED BATTERY. THE BLUE "CHARGE" INDICATOR ON THE FRONT PANEL INDICATES WHEN THE BATTERY IS RECEIVING VOLTAGE TO CHARGE.

Disconnecting Patient Cables

Preamp Cable - Pull the metal outer shell of the connector straight out from the front panel connection on the INVOS Oximeter. The outer shell has a mechanism used to disengage the locking of the two connectors together. **Do not pull on the cable or twist the connector.**

Bilateral Reusable Sensor Cable - Grip the connector while pulling out. Do not pull the cable.

Inspection Points

NOTE: THE INVOS SYSTEM SHOULD BE INSPECTED AT LEAST ONCE EVERY YEAR FOR SAFETY AND NORMAL OPERATION.

Mechanical Inspection Points

Inspect the following for loose screws, cracks, dirt, loose connectors or damaged cords.

- Power cord
- Bilateral Reusable Sensor Cable
- Preamp
- Battery (check for leakage or corrosion)
- Chassis screws
- Rubber feet (replace if missing)
- Keypad
- Fan
- Internal components

NOTE: THE AIR INTAKE ON BOTTOM OF UNIT AND THE FAN SHOULD BE INSPECTED AND VACCUMED IF DUST OR DEBRIS IS PRESENT.

Electrical Inspection Points

Inspection Point	Method
Power Up/Power Down	1. Observe screen for proper functioning and display
Battery Backup	1. Fully charge the battery. 2. Turn the unit on. 3. Unplug line cord (AC Power) and observe that the unit continues to run and that the battery capacity indicator on the screen shows a full charge. The unit should operate for about 2 hours on a fully charged battery.
Unit Self Diagnostics	1. Observe that the unit boots up to the **NEW PATIENT/PREVIOUS PATIENT** screen following power up.
Sensor Operation	1. Follow instructions in Chapter 6. 2. Perform Functional Test with Optional Field Test Device.

Optional Field Test Device Operation

NOTE: ONLY A SOMANETICS SUPPLIED FIELD TEST DEVICE SHOULD BE USED WITH THE INVOS CEREBRAL OXIMETER. NO OTHER FIELD TEST DEVICES SHOULD BE CONNECTED TO THE CEREBRAL OXIMETER. FOR ADDITIONAL INFORMATION ON ACQUIRING AND USING A FIELD TEST DEVICE, CONTACT SOMANETICS' CUSTOMER SERVICE DEPARTMENT AT (248) 689-3050, EXT. 255, VIA WEBSITE AT http::/www.somanetics.com OR VIA EMAIL AT customerservice@somanetics.com.

The field test device allows for functional testing of the INVOS System. To perform a functional test with the Field Test Device:

1. Place the unit on a flat surface where it is protected against falling.
2. Attach appropriate cables to connections shown in Figure 10.1.

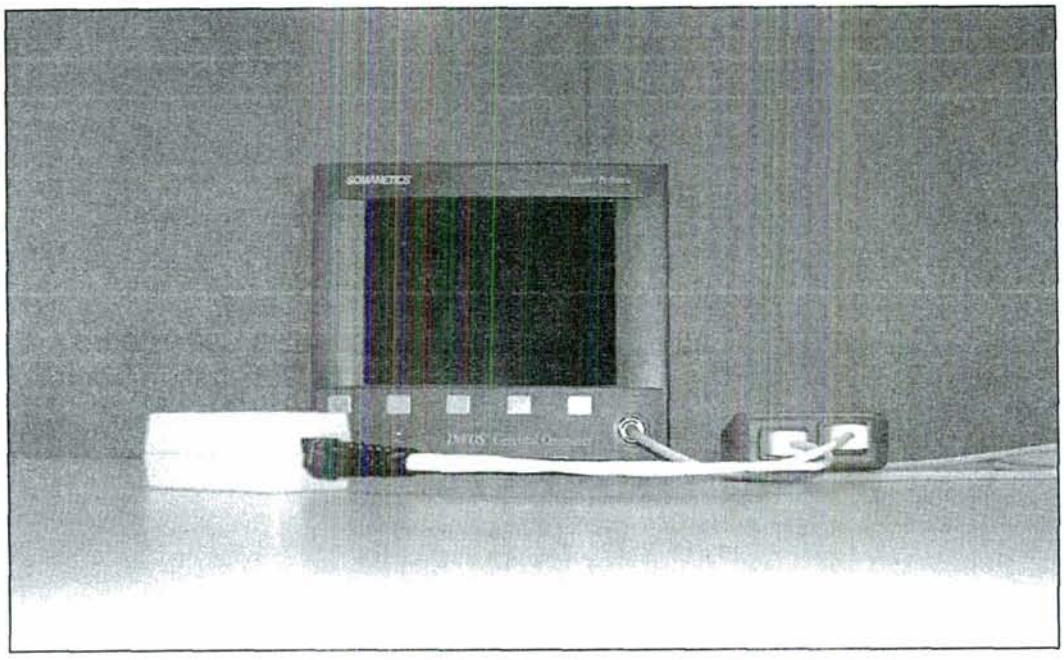


Figure 10.1 Field Test Device Front Panel Connections.

3. Turn on the INVOS System by turning on the line power switch on the rear panel and press **ON/OFF** on the front panel.

NOTE: THE MAINS POWER SWITCH (ON THE BACK PANEL OF THE UNIT) MUST BE LEFT ON AND AC POWER MUST BE CONNECTED AT ALL TIMES TO MAINTAIN THE BATTERY AT FULL CHARGE. THE ∿ BLUE AC POWER INDICATOR SHOWS POWER SWITCH IS ON.

4. When the INVOS System has finished booting up, the "NEW PATIENT/PREVIOUS PATIENT" screen will appear. Press **NEW PATIENT** key to continue past screen.
5. Two channels for data should appear on the screen. The status message will be **SYSTEM SIGNAL OK** and an rSO_2 % of **50±1** for both channels.

Block Diagram

Figure 10.2 shows the block diagram of the INVOS® Cerebral Oximeter. This illustration can be used when attempting to isolate the cause of a problem.

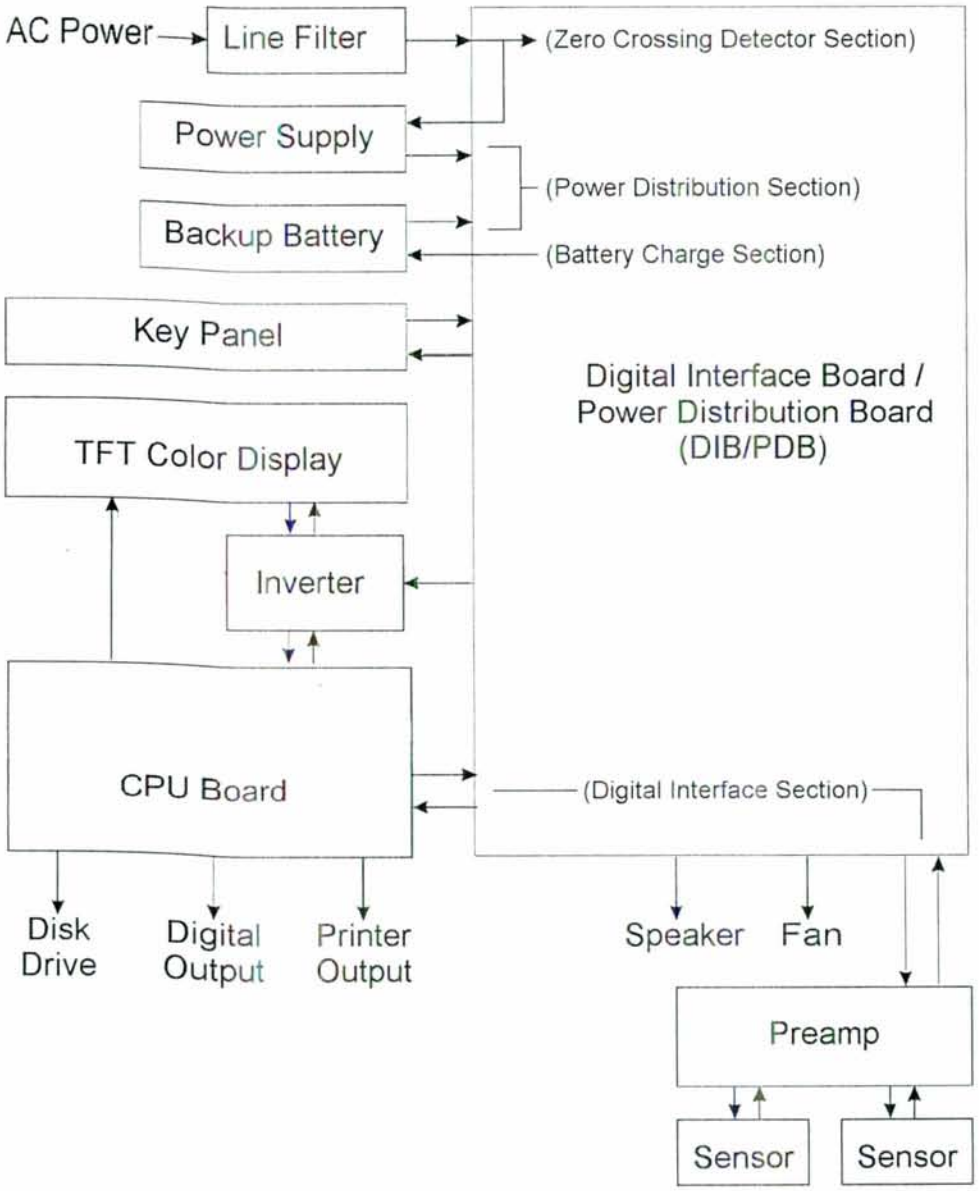


Figure 10.2 Block Diagram of System.

Error Status Messages

The following actions are displayed on the INVOS System screen in response to their respective Error Status Messages. These are actions the user can take to try to correct a problem.

STATUS MESSAGE	ACTION
Sensor Not Connected	Check sensor connection. Check Reusable Cable connection at Preamp.
Excessive Light	Check sensor adhesion. Drape sensor. Reduce room light.
Poor Signal Quality	Check sensor connection for fluid contamination. Remove hair under sensor. Use another medical-grade electrical outlet.
System Signal OK	System operating normally.
Alarm High	Profile patient.
Alarm Low	Profile patient.
Pause Mode	Press RUN/PAUSE key.
Preamp Not Connected	Check Preamp connection at monitor. Replace Preamp.
Com Port Unavailable	Check connections with Com Port device (PC).
Printer Unavailable	Check connections with Printer.
Disk Error	Check connections with Disk Drive.
Replace Sensor	Check for correct sensor type. Connect new sensor. Replace Sensor Cable.
Interference Detected	Noise corrupting rSO_2 data (electrocautery). Move or turn off source of interference.
Disk Full	Replace disk.

Troubleshooting Chart

The chart below provides symptoms that may be encountered while using the INVOS System and a list of the possible causes for each.

INDICATION	PROBLEM	ACTION
Does not Power Up	No AC Power.	Plug INVOS into hospital-grade electrical outlet. Turn on back panel AC power switch.
	Battery not charged.	Charge battery.
	Defective CPU Board.	Service INVOS.*
	Defective Keypad.	Service INVOS.*
	Blown Fuse in Battery Cable or Line Filter.	Service INVOS.*
Locks Up/ Intermittent	Erratic AC Power Input.	Change electrical outlet.
	Defective CPU Card.	Service INVOS.*
No Battery Power	Battery not charged.	Charge battery.
	Defective Battery.	Service INVOS.*
	Defective Power Distribution Section on DIB/PDB Board.	Service INVOS.*
	Blown Fuse in Battery Cable.	Service INVOS.*
Keypads Do Not Function	PRINT option key is pressed.	Wait for print out or turn printer off.
	Defective Keypad.	Service INVOS.*
	Unit locked up.	Reboot INVOS.
	Defective DIB/PDB Board.	Service INVOS.*

Troubleshooting chart continued

INDICATION	PROBLEM	ACTION
No rSO_2 Reading	See Error Messages.	Follow on screen instructions.
	Preamp not connected to Sensor or Oximeter.	Connect sensor or preamp.
	Sensor not connected to patient.	Apply sensor to patient.
	Unit locked up.	Reboot INVOS.
	Defective CPU.	Service INVOS.*
	Defective Preamp Cable or connector.	Service INVOS.*
	Blown Fuse on DIB Board.	Service INVOS.*
	Defective Preamp.	Service INVOS.*
No Display	Defective CPU.	Service INVOS.*
	Defective Display.	Service INVOS.*
	Defective Inverter Board.	Service INVOS.*

*To service the INVOS System, contact Somanetics' Customer Service at (248) 689-3050, ext. 255, email at customerservice@somanetics.com or website at http://www.somanetics.com.

Troubleshooting the Printer

The chart below provides problems that may be encountered while using the Printer and a list of the possible causes and action to correct for each. (See Chapter 8 for Printing Data setup and instructions.)

INDICATION	PROBLEM	ACTION
Pressing the **TURN PRINTER ON** or **CASE HISTORY** key in the **PRINTER** menu produces the **PRINTER UNAVAILABLE** message on the screen	Printer is not connected to Oximeter.	Verify connection of printer to Oximeter.
	The printer is not plugged into AC power and turned on.	Connect power cord and plug AC adapter to AC power.
	The printer is not online.	Press the **On Line** button on the printer.

Troubleshooting the Disk Drive

The chart below provides problems that may be encountered while using the Disk Drive and a list of the possible causes and action to correct for each. (See Chapter 8 for Disk Drive setup, instructions and INVOS System status codes.)

INDICATION	PROBLEM	ACTION
Pressing the **TURN DISK ON** or **CASE HISTORY** key in the **DISK DRIVE** menu does not produces the disk storage rate menu. **DISK ERROR** message appears on the screen.	Disk Drive is not connected to Oximeter.	Verify connection of printer to Oximeter.
	The disk is not formatted.	Check the status of the drive. Insert a disk with IBM formatting.
	The disk is not inserted into the drive.	Check the status of the drive. Insert a blank disk.
	The disk is write-protected.	Slide the write-protection tab back on the disk.

Troubleshooting the Digital Output

The chart below provides problems that may be encountered while Outputting Data and a list of the possible causes and action to correct for each. (See Chapter 8 for Digital Output setup, instructions and INVOS System status codes.)

INDICATION	PROBLEM	ACTION
Pressing the **TURN DIGITAL ON** or **CASE HISTORY** key in the **DIGITAL OUTPUT** menu produces the **COM PORT UNAVAILABLE** message on the screen.	Digital Output Port is not connected to the PC with a null modem cable.	Verify connection of Oximeter to PC with a null modem cable.
	Wrong COM port specified in the Hyper Terminal program.	Verify correct COM port is specified.
No data received or transmission is scrambled.	Hyper Terminal settings not correct.	Verify correct Hyper Terminal settings. See Chapter 8.

Glossary of Terms

A

AC Power

Alternating electric current.

Alarm Limits

Preset and adjustable limits for alarm messages. Alarm tones and a bell symbol will activate if the limits are exceeded.

Authorized Somanetics Repair Personnel

Those individuals authorized by Somanetics to service the INVOS® Cerebral Oximeter.

B

Battery Operation Time

The battery has an approximate 2 hours operation capacity. Recharge time from discharge to full charge is approximately 15 hours.

Bilateral Reusable Sensor Cable

The shielded cable attached to the sensor. Connect this cable to the Preamp.

C

Connection Port

Any of the various inputs or outputs on or relating to the SomaSensor® and the Cerebral Oximeter.

CPU Board

Central Processing Unit Board. Uses application software to control sequencing of the unit and perform diagnostic functions.

D

Default

Indicates the automatically pre-set parameters (field entries) relating to the Cerebral Oximeter. The parameters are adjustable within established limits.

DIB/PDB Board

Digital-Interface and Power-Distribution Board. Controls communication between the Preamp connection, the operator and CPU Board. Distributes power to components and provides voltage to charge the battery.

Distributor

Any of various persons (companies) authorized to distribute the INVOS Cerebral Oximeter in conjunction with agreements between the manufacturer and the distributor.

E

ESD

Electrostatic Discharge

Event

An important occurrence relating to medical operations (such as meds administration, cross clamp, etc.) that can be marked on the INVOS Cerebral Oximeter.

Event Marker

A built-in feature of the Cerebral Oximeter allowing time marking of various events (on a graph or display) that may occur during patient monitoring.

External Preamp Cable

External cable connecting the Preamp port on the faceplate to the Preamplifier.

F

G

H

I

Infrared Light

Light waves just beyond the red end of the visible spectrum.

INVOS®

In Vivo Optical Spectroscopy (INVOS) is the name of the patented technology that Somanetics Corporation uses in the operation of the Cerebral Oximeter.

INVOS® Cerebral Oximeter

A noninvasive, self-contained portable unit that measures the changes in the regional oxygen saturation in the brain of adults and pediatrics. Intended for use with adults and pediatric patients weighing 4 – 40 kg.

J

K

Key

Any of the control push buttons on the INVOS Cerebral Oximeter (membrane switches).

Keypad

The group of keys on the front of the INVOS Cerebral Oximeter.

L

LED

Light Emitting Diode. A semiconductor diode that emits light when voltage is applied.

M

Menu

A detailed list of options available to the user. Menus are found within the Cerebral Oximeter to assist the operator in functions of and variables that can be adjusted.

Multimeter

A meter with voltage, current and resistance measurement functions.

N

O

Optical Spectroscopy

Study of the spectra (series of colors). Relates to the theories behind the INVOS Cerebral Oximeter and the interactions between matter and light.

P

Pause

A stand-by mode during which no data is gathered or stored.

Photodiode

A light sensitive semi-conductor diode used for measurement of light intensity.

Plotting Scales (X and Y Coordinates)

Refers to Y-Scale (rSO_2%) and X-Scale (hours viewed). The two scales combine on the monitor for display of rSO_2 levels over time.

Power Supply Board

Board that accepts incoming AC power from 100-240 volts and converts it to correct DC levels.

Preamp

Pre-Amplifier. Provides connection of flex sensor cable and initial amplification of patient signal.

Q

R

Real-Time

Refers to information displayed immediately on the monitor relating to oxygen saturation levels.

Representative

Any of various persons (companies) authorized to represent the INVOS System in conjunction with agreements between the manufacturer and the representative.

rSO_2

Regional Saturation of Oxygen. Indicates approximate saturation of oxygen within the region being monitored by the INVOS Cerebral Oximeter.

Run

The operation mode. The Cerebral Oximeter is able to monitor and store data in this mode.

S

Sensor

The SomaSensor® is a disposable, non-sterile device applied to the patient and used for transmitting and receiving light.

Skin Prep Kit

A pre-moistened pad (included with the disposable SomaSensor) containing a solution for cleaning the patient's forehead, prior to application of the sensor.

Status Line

Condition or state as relating to operations of the Cerebral Oximeter. The Status Box continually updates and displays the status of the Cerebral Oximeter. Messages on the status line notify the operator of an error (i.e., Check Sensor).

T

Trending Rate

Describes the rate at which data is stored in the Cerebral Oximeter. The Operator has the option of one (1) or two (2) samples per minute. One sample per minute mode has a 24-hour storage limit. Two (2) samples per minute mode has a 12-hour storage limit.

Trend Data

The course of events relating to rSO_2 levels as monitored and displayed by the INVOS Cerebral Oximeter.

Trend Memory

Data generated by the Cerebral Oximeter and displayed chronologically; this data may be printed out for further review.

U

V

W

Wavelength

The distance within the progression of a wave from one point to its corresponding point in the next wave.

X

Y

Z

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312971 SMS209 Pnted in the U.S.A.

SOMANETICS®

Disk Drive Operating Instructions

Cautions/Warnings:

Note: Only a Somanetics supplied disk drive should be used with the INVOS Cerebral Oximeter. No other disk drive devices should be connected to the Cerebral Oximeter. For additional information on acquiring and using a disk drive unit, contact your local Somanetics authorized distributor or call Somanetics Corporation at (800) 359-7662 in the USA or (248) 689-3050 outside the USA.

CAUTION: DO NOT REMOVE THE COVER.
There are no user serviceable parts inside the disk drive.

CAUTION: ELECTRICAL SHOCK WARNING: Unplug the disk drive before cleaning it.

Warning: Do not insert or remove the disk when the Disk Access Light is illuminated. Damage to the disk or the drive could result.

Warning:

- Do Not Autoclave the disk drive.
- Do Not Gas Sterilize the disk drive.
- Do Not Immerse the disk drive in any liquids.

About the Somanetics Disk Drive:

The disk drive duplicates the storage function available in the INVOS® 4100 Cerebral Oximeter with the exceptions that it offers greater capacity, selectable storage rates and stores on a nonvolatile medium suitable for archiving. The disk drive allows Regional Oxygen Saturation (rSO_2) readings to be stored for future review and archiving. It supports the following features and functions:

1. Storage capacity of 3 to 18 days depending on storage rate selected
2. Four different storage rates
3. Non-volatile medium suitable for archiving
4. Stored data can be plotted in a variety of formats

Specifications:

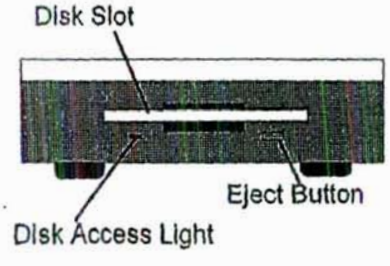
Disk Type:	3.5" Floppy, Double-Sided, High-Density
Disk Capacity:	1.44 MByte
Storage Rate:	User selectable: storage every 10, 15, 30 or 60 seconds
Storage Format:	ASCII Text File, IBM Compatible
Total Storage Capacity:	3 to 18 days depending on storage rate
Power:	Derived from Oximeter

Setup/Installation:

1. Place the unit on a flat surface where it is protected against falling.
2. Attach the disk drive cable to the connector labeled **DISK DRIVE** on the back panel of the Oximeter.
3. The disk drive is now ready to operate.

Operation:

1. Make sure the Disk Drive is installed as described above and the Oximeter is operating (Run or Pause mode) in the Main Menu Display Screen.
2. Insert a blank formatted disk into the disk slot. Use only IBM formatted DS/HD 3.5" Floppy Disks (1.44Mb). Press the front panel menu key on the Oximeter labeled **OUTPUT SELECT,** then **DISK DRIVE**. The Disk Storage Control menu will appear on the Oximeter's screen.



Note: If the **DISK DRIVE** menu key is pressed when the disk drive is not attached a Disk Drive Error message will appear on the Oximeter screen.

3. Use the menu keys to toggle **STORAGE ON** and select the desired **STORAGE RATE.** Press **MAIN MENU** or **RUN/PAUSE** to return to Main Menu Display screen. Disk storage is indicated by the flashing Disk Access Light on the front of the disk drive. It will flash at the storage rate interval.

4. When storage is complete, return to the disk drive control menu and turn off storage before removing the disk. The stored data can be accessed on any IBM or compatible personal computer using a common spreadsheet program like Lotus 1-2-3 or Microsoft Excel. The file will be named **STUFF1.DAT** and will be stored in an ASCII text file in the following format:

Character	1,2,3,4,5,6,7,8	9,10,11,12,13,14,15, 16	17,18, 19	20	21	22,23,24 ,25,26	27,28,29 ,30,31	32,33, 34	35	36
Value	Date	Time	rSO2	Event Marker	Status	D8 count	S8 count	Gain	Carriage Return	Line Feed
Format	M1M2/D1D2/Y1Y2	H1H2:M1M2:S1S2	R1,R2	0/1	0	0.000	0.000	000	CR	LF

Note: The data will be preceded by a "LEFT" or "RIGHT" corresponding to the Oximeter channel that is outputting the data.

It is necessary to parse the data when entering it into a spreadsheet. Follow the software supplier's directions to proceed.

Cleaning:

CAUTION: ELECTRICAL SHOCK WARNING: Disconnect the Disk Drive from the Oximeter before cleaning it.

1. Clean the disk drive cabinet with a dampened cloth (Isopropyl alcohol - 70% or mild soap and water solution).

2. Allow the disk drive to dry before using it.

3. If necessary, the disk drive and cable can be wiped clean with commercial germicidal agents.

Warning:

- Do Not Autoclave the disk drive.
- Do Not Gas Sterilize the disk drive.
- Do Not Immerse the disk drive in any liquids.

Repair Policy:

CAUTION: DO NOT REMOVE THE COVER.
There are no user serviceable parts inside the disk drive.

1. Have all repairs done by Somanetics authorized repair personnel.

2. Damaged or faulty parts will be replaced by Somanetics using original equipment parts (or equivalent).

Contact your local Somanetics distributor for assistance.
If you need further assistance contact Somanetics by phone, fax, or mail:

Customer Service Department
Somanetics Corporation
1653 East Maple Road
Troy, MI 48083-4204

Phone: 248-689-3050 or (800) 359-SOMA.
Fax: 248-689-4272

If you are returning the disk drive, ship it prepaid in the original container as received. **Call and request a return material authorization (RMA) from Somanetics before shipping. Include in Shipment:**

1. A detailed description of the damage and/or malfunctions.
2. The purchase order number or a copy of the purchase order or shipping invoice.
3. The name and phone number of the person to contact within your department.
4. The address of your department and a contact name for the return of the Oximeter to your institution.

Limited Warranty:

Somanetics warrants the Products to be free of defects in material or workmanship resulting in the products failing to meet Somanetics' published specifications at the time of delivery. Claims may be made under this warranty only in the event of failure due to such defect within ninety days of delivery. Terms and conditions of this warranty are detailed in the INVOS Cerebral Oximeter Users Manual.

Troubleshooting:

INDICATION	PROBLEM	ACTION
Pressing the DISK DRIVE key in the OUTPUT SELECT menu does not produce the disk storage control menu.	Disk drive is not connected to Oximeter.	Verify connection of disk drive to Oximeter (see p. 2 of this instruction sheet).
	The disk is not formatted.	Check the status of the drive. Insert a disk with IBM formatting.
	The disk is not inserted into the drive.	Check the status of the drive. Insert a blank disk.
	The disk is write-protected.	Slide the write-protection tab back on the disk.

Setting a Baseline

The Baseline Status can be set to display relative rSO_2 changes from baseline. Both decreases and increases from baseline may signify dysfunction and developing pathology. Changes in rSO_2 of 20% from baseline are considered clinically significant and cause for concern. See Operations Manual, Frequently Asked Questions, Appendix B, for more information.

When trend data begins to be gathered and patient condition is stable, e.g. for surgical patients, prior to induction, a baseline reading should be obtained. To set the baseline, start by pressing the **BASELINE MENU** key on the **MAIN MENU** below the display screen.

BASELINE MENU	EVENT MARK	ALARM SUSPEND	OPTIONS MENU

Figure 1.1 Main Menu.

Press the **BASELINE MENU** key and the following menu options will appear:

BOTH CHANNELS	SET BASELINE	RESET BASELINE	MAIN MENU

Figure 1.2 Baseline Menu.

The first key from the left toggles between **BOTH CHANNELS**, **RIGHT** or **LEFT** channels. Default is **BOTH CHANNELS**. Choose accordingly.

Press the second key from the left to **SET BASELINE**. The baseline value(s) will be set at the current rSO_2 value(s) and the menu will return to the **MAIN MENU**. Also, a two (2) will be placed in the EVENT MARKER column of the digital output and disk drive output data to signify the time and rSO_2 value at baseline capture. See Chapter 8 for output formats.

Press **RESET BASELINE** to restore the most recently set baseline value(s) in the event that a sensor is disconnected and the baseline value erased. The baseline value(s) will not be saved if the INVOS System is turned off.

Operations Manual
INVOS® Cerebral Oximeter
Model 5100B

SOMANETICS®